analyses should be based whenever available on estimates of absorbed doses to tissues and organs, taking full account, to the extent possible, of the circumstances of exposure and the characteristics of the exposed population. Similarly, organ or tissue doses, not effective doses, are required for calculations of probability of causation of cancer in exposed individuals.

(154) In cases of high doses the use of effective dose is inappropriate for the assessment of tissue reactions. In such situations it is necessary to estimate absorbed dose and to take into account the appropriate RBE as the basis for any assessment of radiation effects (see Annex B).

4.4.7. Collective dose

(155) For the purpose of optimisation of radiological protection, the Commission has introduced the collective dose quantities (ICRP, 1977; 1991). These quantities take account of the group of persons exposed to radiation and the period of exposure. They are obtained as the sum of all individual doses over a specified time period from a source. The specified quantities have been defined as the collective equivalent dose, S_T, which relates to a tissue or an organ T, and the collective effective dose, S (ICRP, 1991). The special name used for the collective dose quantity is the 'man sievert'. Since the intention of the collective dose is to serve as an instrument in the optimisation of radiological protection only the collective effective dose is retained in the present system.

(156) The collective effective dose, S, is based on the assumption of a linear dose effect relationship for stochastic effects without a threshold (the LNT concept). Under these conditions it is possible to regard effective doses as additive.

(157) Collective effective dose is an instrument for optimisation, for comparing radiological technologies and protection procedures. Collective effective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections for such studies. Specifically, the computation of cancer deaths based on collective doses involving trivial exposures to large populations is not reasonable and should be avoided. Such computations based on collective effective dose were never intended and are an incorrect use of this radiological protection quantity.

(158) To avoid aggregation of, e.g., very low individual doses over extended time periods and wide geographical regions, limiting conditions need to be set. The dose range and the time period should be stated. The collective effective dose due to individual effective dose values between E_1 and E_2 is defined as:

$$S(E_1, E_2, \Delta T) = \int_{E_1}^{E_2} E \frac{\mathrm{d}N}{\mathrm{d}E} \mathrm{d}E \qquad (4.12)$$

where $\mathrm{d}N/\mathrm{d}E$ denotes the number of individuals who are exposed to an effective dose between E and $E + \mathrm{d}E$ and ΔT specifies the time period within which the effective doses are summed (see Annex B).

4.5 Uncertainties and judgements

(159) In the evaluation of radiation doses, models are necessary to simulate the geometry of the external exposure, the biokinetics of the intake and retention of radionuclides in the human body, and the human anatomy. These models and their parameter values have been developed in many cases from experimental investigations and human studies in order to derive 'best estimates' or 'central estimates' of model parameter values. Similar considerations apply to the choice of tissue and radiation weighting factors. It is recognised that there are appreciable uncertainties in the values of some of the parameters and in the formulation or structures of the models themselves. Judgement is needed on the best choice of the necessary parameters for dose assessments (see Annex B).

(160) Uncertainty refers to the level of confidence that can be placed in a given parameter value or prediction of a model. It is an important factor in all extrapolation procedures. In this connection the variability of individual parameters and the accuracy of measurements are also of great importance. The accuracy of measurements and judgements will become less with decreasing doses and increasing complexity of the system. Variability refers to quantitative differences between individual members of the population in question. All these aspects are taken into account in model development in the judgements (see Annex B).

(161) The lack of certainty or precision in radiation dose models varies for the various parameters and the circumstances in defined situations. Therefore it is not possible to give values for the uncertainties across the range of ICRP models, despite the fact that their assessment is an important part of model development. Uncertainties may need to be assessed, however, for special cases, and approaches to their use have been described in a number of publications e.g., (Goossens et al., 1997; CERRIE 2004, ICRP 1994, 2006, Bolch et al., 2003, Farfan et al., 2005). In general it can be said that uncertainties for assessments of radiation doses from internal exposures including the biokinetics of radionuclides are larger than those from external exposures. The degree of uncertainty differs between various radionuclides.

(162) The Commission is aware of the lack of certainty or precision in radiation dose models and efforts are undertaken to critically evaluate and to reduce them wherever possible. In regulatory processes, the dosimetric models and parameter values that the Commission recommends are fixed by convention and are therefore not subject to uncertainty. Equally the Commission considers that the biokinetic and dosimetric models which are needed for the purpose of dose assessment are defined as reference data and, therefore, are not uncertain. These models and values are re-evaluated periodically and may be changed by ICRP on the basis of such evaluations when new scientific data and information are available.

(163) Regulatory compliance is determined using point estimates of effective dose that apply to reference persons, regarding these point estimates as subject to no uncertainties. In retrospective assessments of doses that may approach or exceed limits, it may be considered appropriate to make specific individual estimates of dose and risk and also to consider uncertainties in these estimates.

(164) Despite changes in dosimetric modelling, as well as differences in the computation of effective dose, previous assessments of equivalent dose or effective

dose should be considered adequate. The Commission does not recommend re-computation of existing values with the new models and parameters.

5. THE SYSTEM OF RADIOLOGICAL PROTECTION OF HUMANS

(165) In dealing with radiological situations, it is convenient to think of the processes causing human exposures as a network of events and situations. Each part of the network starts from a source. Radiation or radioactive material then passes through environmental pathways leading to the exposure of individuals. Finally, the exposure of individuals to radiation or radioactive materials leads to doses to these individuals. Protection can be achieved by taking action at the source, or at points in the exposure pathways, and occasionally by modifying the location or characteristics of the exposed individuals. For convenience, the environmental pathway is usually taken to include the link between the source of exposure and the doses received by the individuals. The available points of action have a substantial effect on the system of protection.

(166) Everybody is exposed to ionising radiation from natural and man-made sources. In its totality, this network is unmanageable. Fortunately, the assumed proportional relationship between an increment of dose and an increment of risk of stochastic effects makes it possible to deal separately with parts of the network and to select those parts that are of relevance in a given situation. To make these selections, however, it is necessary to define for each part of the network the objectives, the organisations (and individuals) responsible for protection, the lines of responsibility, and the feasibility of obtaining the necessary information. This remains a complex procedure, and the Commission suggests two simplifications in managing radiological situations.

(167) The first simplification was used in the 1990 Recommendations and recognises that individuals are exposed to several categories of exposure, which can be dealt with separately (ICRP, 1991). For example, most workers who are exposed to radiation sources as part of their work are also exposed to environmental sources as members of the public, and to medical exposure as patients. The Commission's policy continues to be that the control of exposures due to work need not be influenced by the exposures from these other sources. This policy is still reflected in the new recommendations by the separation of the exposure into three categories: occupational exposure, medical exposure of patients, and public exposure (see Section 5.3). The Commission continues to recommend that no attempt be made to add the exposures to the same individual from the different categories of exposure.

(168) The second simplification is that in dealing with the network of prolonged exposure pathways, a distinction is drawn between source-related considerations and individual-related considerations. Although within each category of exposure individuals can be exposed to several sources, for the purpose of protection procedures to be applied to the sourcem each source, or group of sources, can be treated on its own (ICRP, 1991b). It is then necessary to consider the exposure of all the individuals who could be exposed by this source or group of sources. This procedure is called a 'source-related assessment' (see Section 5.5).

(169) For the practical control of exposures, in *Publication 60* the network of events and situations causing these exposures was divided in two broad classes of situations: practices and interventions. Practices were defined as human activities increasing exposure either by introducing whole new blocks of sources, pathways, and individuals, or by modifying the network of pathways from existing sources to

man and thus increasing the exposure of individuals or the number of individuals exposed. Interventions were defined as human activities that decrease the overall exposure by influencing the existing form of the network. These activities may remove existing sources, modify pathways or reduce the number of exposed individuals. In the revised system of protection the Commission now moves from such a process based approach to an approach based on the characteristics of three types of radiation exposure situation, i.e., planned, emergency, and existing exposure situations.

5.1. The definition of a source

(170) The Commission uses the term 'source' to indicate any physical entity or procedure that results in a potentially quantifiable radiation dose to a person or group of persons. It can be a physical source (e.g., radioactive material or an x-ray machine), a facility (e.g., a hospital or nuclear power plant), or a class of operations or physical sources having similar characteristics (e.g., maintenance work in an installation, nuclear medicine procedures, background or environmental radiation). If radioactive substances are released from an installation to the environment, the installation as a whole may be regarded as a source; if they are already dispersed in the environment, the portion of them to which people are exposed may be considered a source. Most situations will give rise to a predominant source of exposure for any single individual, or representative person, making it possible to treat sources singly when considering actions. Provided that the user and the regulator both apply the spirit of the Commission's broad policies, the definition of a source is straightforward.

(171) In general, the definition of a source will be linked to the selection of relevant constraints or reference levels, as appropriate, for optimisation. Difficulties will arise if the policy is distorted, e.g. by artificially subdividing a source in order to avoid the need for protective action, or by excessively aggregating sources to exaggerate the need for action.

5.2. Types of exposure situations

(172) The Commission intends its recommendations to be applied to all sources and to individuals exposed to radiation in the following three types of exposure situations which address all conceivable circumstances:

- *Planned exposure situations* are situations involving the planned introduction and operation of sources. This would also include their decommissioning, disposal of associated radioactive waste, and rehabilitation of the previously occupied land in the case of installations. Planned exposure situations include both normal exposures and potential exposures insofar as the latter comply with pertinent risk constraints.

- *Emergency exposure situations* are unexpected situations that occur during the operation of a planned situation, or from a malicious act, requiring urgent action.

- *Existing exposure situations* are exposure situations that already exist when a decision on control has to be taken, including natural background radiation and

residues from past practices that have been operated outside the Commission's recommendations, or long-term exposure situations.

It follows that what the Commission has called 'practices' could be the origin of planned, emergency, and existing exposure situations. In principle, planned exposure situations also include medical exposures of patients, but because of the characteristics of such exposures, they are discussed separately. The principles of protection for planned situations also apply to planned work in connection with existing and emergency exposure situations.

5.3. Categories of exposure

(173) The Commission distinguishes between three categories of exposures; occupational exposures, public exposures, and medical exposures of patients.

5.3.1. Occupational exposure

(174) Occupational exposure is defined by the Commission as all radiation exposure of workers incurred as a result of their work. Excluded exposures and exposures from exempt practices or exempt sources generally do not need to be accounted for in the calculation of occupational exposure. The Commission has noted the conventional definition of occupational exposure to any hazardous agent as including all exposures at work, regardless of their source. However, because of the ubiquity of radiation, the direct application of this definition to radiation would mean that all workers should be subject to a regime of radiological protection. The Commission therefore limits its use of 'occupational exposures' to radiation exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management.

(175) The employer has the main responsibility for the protection of workers. However, the licensee (if not identical to the employer) also has a responsibility for the occupational exposure. If workers are engaged in work that involves, or could involve, a source that is not under the control of their employer, the licensee responsible for the source and the employer should cooperate by the exchange of information and otherwise as necessary to facilitate proper radiological protection at the workplace.

5.3.2. Public exposure

(176) Public exposure encompasses all exposures other than occupational and medical exposures of patients (see Section 5.3.3). It is incurred as a result of a range of radiation sources. The component of public exposure due to natural sources is by far the largest, but this provides no justification for reducing the attention paid to smaller, but more readily controllable, exposures to man-made sources.

5.3.3. Medical exposure of patients including their comforters and carers

(177) Radiation exposures of patients can occur in diagnostic, screening, interventional, and therapeutic procedures. There are several features of radiological practices in medicine that require an approach that differs from the radiological protection in other planned exposure situations. The exposure is intentional and for the direct benefit of the patient. Particularly in radiotherapy, the biological effects of

high-dose radiation, e.g., cell killing, are used for the benefit of the patient to treat cancer and other diseases. The application of these recommendations to the medical uses of radiation therefore requires separate guidance.

5.4. The identification of the exposed individuals

(178) It is necessary to deal separately with at least three categories of exposed individuals, namely workers, the public, and patients. They essentially correspond to individuals whose exposures fall into the three categories of exposure defined in Section 5.3. A given individual can be exposed as a worker, and/or as a member of the public, and/or as a patient.

5.4.1. Workers

(179) A worker is defined by the Commission as any person who is employed, whether full time, part time or temporarily, by an employer and who has recognised rights and duties in relation to occupational radiological protection. A self-employed person is regarded as having the duties of both an employer and a worker.

(180) One important function of an employer is that of maintaining control over the sources of exposure and over the protection of workers who are occupationally exposed. In order to achieve this, the Commission recommends the classification of areas of work rather than the classification of workers. Requiring that the areas of workplaces containing sources be formally designated helps their control. The Commission uses two such designations: *controlled areas* and *supervised areas*. A controlled area is one in which normal working conditions, including the possible occurrence of minor mishaps, require the workers to follow well-established procedures and practices aimed specifically at controlling radiation exposures. A supervised area is one in which the working conditions are kept under review but special procedures are not normally needed.

(181) Workers in 'controlled areas' of workplaces should be well informed and specially trained, and form a readily identifiable group. Such workers are most often monitored for radiation exposures incurred in the workplace, and occasionally may receive special medical surveillance.

The exposure of pregnant workers

(182) In the 1990 Recommendations, the Commission concluded that for the purpose of controlling occupational exposure, there was no reason to distinguish between the two sexes. The Commission does not deviate from this policy with these new recommendations. However, if a female worker has declared that she is pregnant, additional controls have to be considered to protect the embryo/fetus. It is the Commission's policy that the methods of protection at work for women who are or may be pregnant should provide a level of protection for the embryo/fetus similar to that provided for members of the public. The Commission considers that this policy will be adequately applied if the mother is exposed, prior to her declaration of pregnancy, under the system of protection recommended by the Commission. Once pregnancy has been declared, and the employer notified, additional protection of the embryo/fetus should be considered. The working conditions of a pregnant worker, after declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the fetus would exceed about 1 mSv during the remainder of the pregnancy. Additional guidance on protection of the fetus is provided in Section 7.4.

(183) The restriction of the dose to the fetus does not mean that it is necessary for pregnant women to avoid work with radiation or radioactive materials completely, or that they must be prevented from entering or working in designated radiation areas (see paragraph 180). It does, however, imply that the employer should carefully review the exposure conditions of pregnant women. In particular, their employment should be of such a type that the probability of accidental doses and radionuclide intakes is extremely low. Specific recommendations on the control of exposures to pregnant workers are given in *Publication 84* and *88* (ICRP, 2001a,b). The Commission has also published information in *Publication 95* (ICRP, 2004b) that enables doses to offspring following intakes to breast-feeding mothers to be calculated. The Commission recommends that in order to protect the embryo/fetus or infant, females who may be pregnant or are nursing should not be involved in emergency actions involving high radiation doses. (ICRP, 2005).

(184) In *Publication 88* (ICRP, 2001b), the Commission gave dose coefficients for the embryo, fetus, and newborn child from intakes of radionuclides by the mother before or during pregnancy. In general, doses to the embryo, fetus, and newborn child are similar to or less than those to the reference adult person; however, there are exceptions where the dose can exceed that of the reference adult by a factor of around 10. In *Publication 95* (ICRP, 2004b) the Commission provided information on radiation doses to the breast-feeding infant due to intakes of radionuclides in maternal milk. For most of the radionuclides considered, doses to the infant from radionuclides ingested in breast milk are estimated to be small in comparison with doses to the reference adult. It is rare that the dose to the newborn child can exceed that of the reference adult by a factor of more than about three.

5.4.2. Members of the public

(185) A member of the public is defined by the Commission as any individual who receives an exposure that is neither occupational nor medical (see also Section 5.4.3). Furthermore, the embryo/fetus should be afforded a level of protection similar to that of a member of the public. A large range of different natural and man-made sources is contributing to the exposure of members of the public.

(186) In general, especially for public exposure, each source will result in a distribution of doses over many individuals. For the purposes of protection of the public, the Commission has used the 'critical group' concept to characterise an individual receiving a dose that is representative of the more highly exposed individuals in the population (ICRP 1977, 1985). Dose restrictions have been applied to the mean dose in the appropriate critical group. Over the last decades, there have been developments in the techniques used to assess doses to members of the public, notably the increasing use of probabilistic techniques. There has also been a considerable body of experience gained in the application of the critical group concept. The adjective 'critical' has the connotation of a crisis, which was never intended by the Commission. Second, the word 'group' may be confusing in the context that the assessed dose is the dose to an individual, whether hypothetical or an actual member of the public. The Commission now recommends the use of 'the representative person' for the purpose of radiological protection of the public instead of the earlier critical group concept. The Commission provides guidance on characterising the 'representative person' and assessing doses to the representative person in *Publication 101* (ICRP, 2006b).

(187) The representative person may be hypothetical. Nevertheless, it is important that the habits (e.g. consumption of foodstuffs, breathing rate, location, usage of local resources) used to characterise the representative person are typical habits of a small number of individuals representative of those most highly exposed and not the extreme habits of a single member of the population. Consideration may be given to some extreme or unusual habits, but they should not dictate the characteristics of the representative persons considered.

5.4.3. Patients, including their comforters and carers

(188) The Commission defines the patient as an individual who receives an exposure associated with a diagnostic, screening, interventional, or therapeutic procedure. The Commission's dose limits and dose constraints are not recommended for individual patients because they may reduce the effectiveness of the patient's diagnosis or treatment, thereby doing more harm than good. The emphasis is therefore on the justification of the medical procedures and on the optimisation of protection ant the use of diagnostic reference levels (see Chapter 7).

(189) The exposure of patients who may be pregnant is dealt with in Section 7.4.

5.5. Levels of radiological protection

(190) Even within a single type of exposure (occupational / public / medical), an individual may be exposed by several sources, so an assessment of the total exposure has to be attempted. It is not always possible to carry out such an assessment comprehensively. Generally, only a small number of the relevant sources can be identified and quantified. This should, however, include all exposures to individuals from(ny variant) regulated sources causing substantial exposures to the individual. This approach is called *'individual-related'*.

(191) In the 1990 Recommendations, it was suggested that each regulated source or group of sources could usually be treated on its own. It is then necessary to consider the exposure of all the individuals exposed by this source or group of sources. This procedure is called a *'source-related'* approach. The Commission now emphasises the primary importance of the source-related approach, since action can be taken for a source to assure the protection of a group of individuals from that source. An appropriate level of protection from sources is achieved by optimisation using dose constraints in planned exposure situations and using reference levels in emergency or existing exposure situations (see Section 5.9)

(192) Planned exposure situations, however, involve the exposure of individuals with a magnitude that can be foreseen in advance, albeit with some uncertainty. This element of deliberate exposure distinguishes these exposure situations from existing and emergency situations. Sole reliance on source-related restrictions may not afford sufficient protection as individuals could be exposed to a number of different sources in planned exposure situations. Therefore, a restriction on the sum of the doses from sources in planned exposure situations is required. The Commission refers to these individual-related restrictions as dose limits.

(193) It is rarely possible to assess the total exposure of an individual from all such sources. It is therefore necessary to make approximations to the dose to be compared with the quantitative limit, especially in the case of public exposure. For

occupational exposures, the approximations are more likely to be accurate because the operating management has access to the necessary information to identify and control the dose from all the relevant sources. Figure 2 illustrates the differences in concept between individual dose limits and constraints or reference levels for protection from a source in all situations and the use, in planned situations only, of individual-related dose limits.

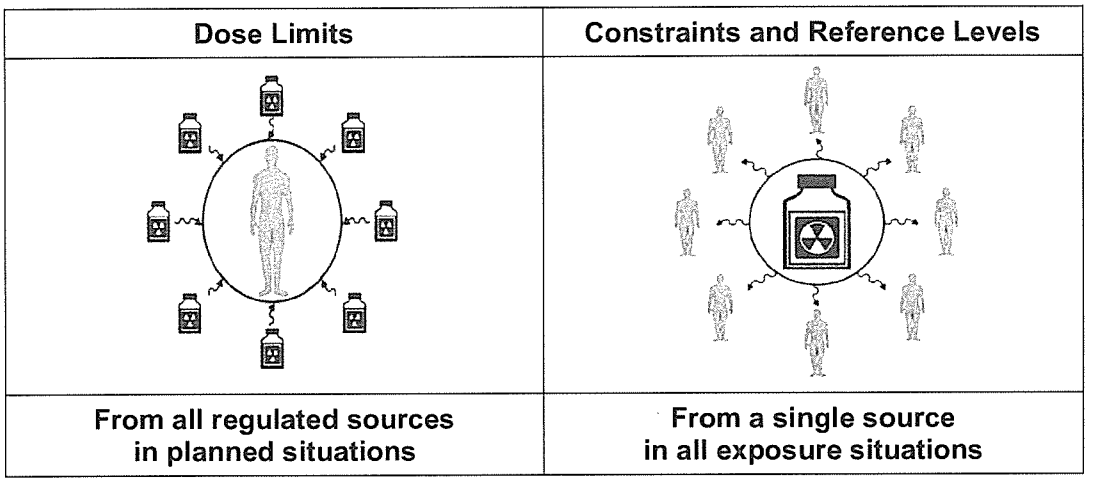

Fig. 2. Dose limits compared with dose constraints and reference levels to protect members of the public or workers.

(194) For planned exposure situations, the source-related restriction to the dose that individuals may incur is the *dose constraint*. For potential exposures, the corresponding concept is the *risk constraint*. For emergency and existing exposure situations, the source-related restriction is the reference level (see Chapter 6). The concepts of a dose constraint and reference level are used in conjunction with optimisation of protection to assure that all exposures are kept as low as reasonably achievable, social and economic factors being taken into account. Constraints and reference levels can thus be described as key tools in the optimisation process that will assure appropriate levels of protection under the prevailing circumstances.

(195) In the case of radiation exposures due to intakes, the term 'dose' in the Commission's quantitative recommendations implies the committed dose, i.e., including the appropriate time integral of the dose rate (cf. Section 4.4). The dose is thus defined as the sum of the time integral, over a year, of the effective dose rate due to external irradiation caused by a exposure situation, and the committed effective dose due to internal contamination from any intakes, during the year, of the radionuclides involved in the situation.When the Commission refers to dose accumulated in a given period of time, it is implicit that any committed doses from intakes occurring in that same period are included.

5.6. The principles of radiological protection

(196) In the 1990 Recommendations, the Commission gave principles of protection for practices separately from intervention situations. The Commission continues to regard these principles as fundamental for the system of protection, and has now formulated a set of principles that apply to planned, emergency, and existing controllable situations. In the new recommendations, the Commission also

clarifies how the fundamental principles apply to radiation sources and to the individual, as well as how the source-related principles apply to all controllable situations.

Two principles are source related and apply in all situations:

- **The principle of justification:** Any decision that alters the radiation exposure situation should do more good than harm.

  This means that by introducing a new radiation source or by reducing existing exposure, one should achieve an individual or societal benefit that is higher than the detriment it causes.

- **The principle of optimisation of protection:** the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.

  This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk reference levels and constraints).

One principle is individual related and applies in planned situations:

- **The principle of application of dose limits:** The total dose to any individual from all planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

(197) Dose limits are determined by the national regulatory authority on the basis of international recommendations and apply to workers and to members of the public in planned exposure situations. Dose limits do not apply to medical exposure of patients, or to public exposures in emergency situations, or to existing exposure situations.

5.7. Justification

(198) Justification is a necessary prerequisite for any decision regarding radiological protection actions.

(199) The Commission recommends that, when activities involving an increased or decreased level of radiation exposure, or a risk of potential exposure, are being considered, the expected change in radiation detriment should be explicitly included in the decision-making process. The negative consequences to be considered are not confined to that associated with the radiation – it includes other risks and the costs of the activity. Often, the radiation detriment will be a small part of the total. The justification should also include the analysis if other techniques that do not require exposure to ionising radiation are more appropriate. Justification thus goes far beyond the scope of radiological protection. It is for these reasons that the Commission limits its use of the term justification to require that the net benefit be positive. To search for the best of all the available alternatives is usually a task beyond the responsibility of radiological protection authorities.

(200) There are two different approaches to applying the principle of justification in situations involving occupational and public exposure, which depend upon whether or not the source can be directly controlled. The first approach is used in the introduction of planned situations where radiological protection is planned in advance and the necessary actions can be taken on the source. Application of the justification principle to these situations requires that no planned situation should be introduced unless it produces sufficient net benefit to the exposed individuals or to society to offset the radiation detriment it causes. In this context, a planned situation is a generic type of practice, the essential features of which are common to specific practices of the same type. Judgements on whether it would be justifiable to introduce or continue particular types of practice involving exposure to ionising radiation are important. Alternatives to existing practices may develop overtime, which would probably require these to be periodically re-examined to ensure that they are still justified.

(201) The second approach is used where exposures can be controlled mainly by action to modify the pathways of exposure and not by acting directly on the source. The main examples are existing and emergency exposure situations. In these circumstances, the principle of justification is applied in making the decision as to whether to take action to avert further exposure. Any decision taken to reduce doses, which always have some disadvantages, should be justified in the sense that they should do more good than harm.

(202) In both approaches, the responsibility for judging the justification usually falls on governments or national authorities to ensure an overall benefit in the broadest sense to society and thus not to each individual. However, input to the justification decision may include many aspects that could be informed by users or other actors outside of government. As such, justification will generally be carried out through appropriate social processes, depending upon, among other things, the size of the source concerned. There are many aspects of justification, and different organisation may be involved and responsible. For example, the operator may justify the building of a power plant based on economic considerations, while the government may be concerned more with safety considerations. In this context, radiological protection considerations will serve as one input to the broader decision process.

(203) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation should be justified, as is any other planned situation, although that justification lies more often with the profession than with government or the competent regulatory authority. The principal aim of medical exposures is to do more good than harm to the patient, due account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals. The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners, who need to have special training in radiological protection. Justification of medical procedures therefore remains part of the Commission's Recommendations (see Section 7.1).

5.7.1. Unjustified procedures

(204) The Commission considers that certain procedures could be deemed to be unjustified without further analysis, unless there are exceptional circumstances supporting the use of those procedures. These include:

- Increasing, by deliberate addition of radioactive substances or by activation, the activity of commodities or consumer products, such as food, beverages, cosmetics, toys, and personal jewellery or adornments.
- Radiological examination for occupational, legal, or health insurance purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined, or the specific type of examination is justified by those requesting it in consultation with relevant professional bodies. This means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified.
- Mass screening of population groups involving radiation exposure, unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and societal costs, including the radiation detriment, account being taken of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected, and, for certain diseases, the advantages to the community of control of the disease.

5.8. Optimisation of protection

(205) The process of optimisation of protection is intended for application to those protective actions that have been deemed to be justified. The principle of optimisation of protection with a restriction on individual dose is central to the system of protection applying to all three exposure situations: planned situations, emergency situations, and existing exposure situations. This principle has been applied very successfully in planned situations (specifically practices) where protective actions can be initiated at the design stage. The Commission's intention is to extend this experience to the other two types of exposure situations, the emergency and existing exposure situations. The dose constraints and reference levels are important tools to aid optimisation of protection in all three exposure situations.

(206) The principle of optimisation is defined by the Commission as the source related process to keep the likelihood of incurring exposures where these are not certain to be received, the number of people exposed, and the magnitude of individual doses as low as reasonably achievable below the appropriate risk and dose constraints or reference levels, taking into account economic and societal factors.

(207) The Commission has earlier provided guidance on how to apply the optimisation principle mainly for planned situations (ICRP, 1983, 1988, and 1991b), and these recommendations remain valid. The decision aiding techniques are still essential to find the optimised radiological protection solution in an objective manner; theses techniques include methods for quantitative optimisation such as cost-benefit analyses. However, the way the principle of optimisation should be implemented is now viewed as a broader process encompassing the protection of

individuals, safety culture and the involvement of concerned parties (ICRP, 1998, 1999). The Commission is aware that this approach reflects the way in which many users are currently applying the principle of optimisation in planned exposure situations.

(208) The optimisation must be implemented through an on-going, iterative process that involves the:

- evaluation of the exposure situation to identify the need for action (the framing of the process);
- selection of an appropriate value for the constraint or reference level;
- identification of the possible protection options to keep the exposure as low as reasonably achievable;
- selection of the best option under the prevailing circumstances taking account of the constraint or reference level;
- implementation of the selected option through an effective optimisation programme;
- regular reviews of the exposure situation to evaluate if the prevailing circumstances call for the implementation of corrective protection actions; and
- consideration of the avoidance of emergencies and other potential exposures for planned situations.

(209) Experience has shown how optimisation of protection has improved radiological protection outcomes for some planned situations. Constraints provide a desired bound for the optimisation process. Some sources and technologies are able to satisfy constraints that are set at a low level, while others are only able to meet constraints set at a higher level: this is normal, and should be reflected in the freedom of national authorities to authorise dose constraints that are appropriate for particular circumstances.

(210) In all situations, the process of optimisation with the use of constraints or reference levels is applied in planning protective actions and in establishing the appropriate level of protection under the prevailing circumstances. The doses to be compared with the dose constraint or reference levels are usually prospective doses, i.e., doses that may be received in the future, as it is only those doses that can be influenced by decisions on protective actions. They are not intended as a form of retrospective dose limit, even if they are considered in the feedback process. The optimisation processes should be interactive and iterative involving users and national authorities.

(211) The optimisation of protection is a forward-looking iterative process aimed at preventing or reducing future exposures. It is continuous, taking into account both technical and socio-economic developments and requires both qualitative and quantitative judgements. The process should be systematic and carefully structured to ensure that all relevant aspects are taken into account. Optimisation is a frame of mind, always questioning whether the best has been done in the prevailing circumstances, and if all that is reasonable has been done to reduce doses. It also requires the commitment at all levels in all concerned organisations as well as adequate procedures and resources.

(212) The best option is always specific to the exposure situation and represents the best level of protection that can be achieved under the prevailing circumstances. Therefore it is not relevant to determine, *a priori*, a dose level below which the optimisation process should stop. Depending on the exposure situation, the best option could be close to or well below the appropriate source-related constraint or reference level. This means that the optimisation process may result in doses lower than any level that could be proposed as an 'entry level' into the system of radiological protection.

(213) Optimisation of protection is not minimisation of dose. Optimised protection is the result of an evaluation, which carefully balances the detriment from the exposure (economic, human, societal, political, etc.) and the resources available for the protection of individuals. Thus the best option is not necessarily the one with the lowest dose.

(214) In addition to the reduction of the magnitude of individual exposures, a reduction of the number of exposed individuals should also be considered. The comparison of protection options for the purpose of optimisation must entail a careful consideration of the characteristics of the individual exposure distribution within an exposed population. A particular issue is the one related to the comparison of the distribution of the exposures over long time periods and future populations.

(215) When the exposures occur over large populations, large geographical areas, or long time periods, the total collective effective dose is not a useful tool for making decisions because it may aggregate information excessively and could be misleading for selecting protection actions. To overcome the limitations associated with collective effective dose, each relevant exposure situation must be carefully analysed to identify the individual characteristics and exposure parameters that best describe the exposure distribution among the concerned population for the particular circumstance. Such an analysis– by asking when, where and by whom exposures are received – results in the identification of various population groups with homogeneous characteristics for which collective effective doses can be calculated within the optimisation process.

(216) In *Publications 77* and *81* (ICRP, 1998a; 2000a), the Commission recognised that both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, less weight could be given to very low doses and to doses received in the distant future. The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out.

(217) All aspects of optimisation cannot be codified; optimisation is more an obligation of means than of results. It is not the role of the regulatory authority to focus on specific outcomes for a particular situation, but rather on processes, procedures, and judgements. An open dialogue must be established between the authority and the operating management, and the success of the optimisation process will depend strongly on the quality of this dialogue.

5.9. Dose constraints and reference levels

(218) The concepts of *dose constraint* and *reference level* apply to any exposure situation (i.e., planned, emergency, or existing) and are used in conjunction with the optimisation of protection to restrict individual doses (even if this precludes some protection options entailing lower collective doses). A level of individual dose always needs to be defined, above which one plans not to go (or, for existing exposure situations, not to stay), and below which one strives to reduce all actual doses. All exposures, above or below this level of individual dose, are subject to optimisation of protection.

(219) For the sake of continuity with its earlier Recommendations (ICRP, 1991), the Commission retains the term 'dose constraint' for this level of dose in planned exposure situations (with the exception of medical exposure of patients). For emergency and existing exposure situations, the Commission proposes the term 'reference level' to describe this level of dose. The difference in terminology between planned and other exposure situations (emergency and existing) has been retained by the Commission to express the fact that the restriction on individual doses can be complied with from the beginning of the optimisation process in planned situations, while with the other situations the optimisation process may apply to levels of individual doses above the reference level. Diagnostic reference levels are already being used in the medical diagnosis (i.e., planned situations) to indicate whether, in routine conditions, the levels of patient dose or administered activity from a specified imaging procedure are unusually high or low for that procedure. If so, a local review should be initiated to determine whether protection has been adequately optimised or whether corrective action is required.

(220) The important message from the Commission is that a similar approach is used in optimisation, regardless of the type of source or the exposure situation. By increasing the attention to the process of optimisation in all radiation exposure situations, the Commission is of the opinion that the level of protection for what has until now been categorised as interventions will be improved, compared to the recommendations in *Publication 60* (ICRP, 1991).

(221) Thus, the chosen value for a constraint or a reference level will depend upon the prevailing circumstances of the exposure under consideration. It must also be realised that neither of them represent a demarcation between 'safe' and 'dangerous' or reflect a step change in the associated health risk for individuals.

(222) In Table 4 the different types of dose restrictions used in the Commission's system of protection (limits, constraints, reference levels) are shown in relation to type of exposure situation and category of exposure.

Table 4. The types of dose restrictions used in the Commission's system of protection in relation to type of exposure situation and category of exposure.

Type of situation	Occupational Exposure	Public Exposure	Medical Exposure
Planned exposure	Dose limit Dose constraint	Dose limit Dose constraint	Diagnostic reference level
Emergency exposure	Reference level[a]	Reference level	N.A.[b]
Existing exposure	Reference level	Reference level	N.A.[b]

[a] Long-term recovery operations should be treated as part of planned occupational exposure
[b] Not applicable

5.9.1. Dose constraints

(223) A dose constraint is a prospective and source related restriction on the individual dose from a source in planned exposure situations (except in medical exposure of patients), which serves as an upper bound on the dose in the optimisation of protection for that source. Dose constraints for planned situations represent a basic level of protection and will always be lower than the pertinent dose limit. During planning it must be ensured that the source concerned does not imply doses exceeding the constraint; optimisation of protection will establish a level of dose below the constraint.

(224) A dose constraint can be defined as a level of dose above which it is unlikely that protection is optimised for a given source of exposure, and for which, therefore, action must almost always be taken. The action necessary if a dose constraint is exceeded would normally begin by determining whether protection has been optimised, and if it has not, should include taking steps to reduce doses to acceptable levels. For potential exposures this source-related restriction is called a risk constraint (see Section 6.1.3). Compliance with the dose constraint is not sufficient, and optimisation of protection will be necessary to establish an acceptable level of dose below the constraint.

(225) The concept of dose constraints was introduced in *Publication 60* as a means to assure that the optimisation process did not create inequity, i.e. the possibility that some individuals in an optimised protection scheme may be subject to much more exposure than the average:

'Most of the methods used in the optimisation of protection tend to emphasise the benefits and detriments to society and the whole exposed population. The benefits and detriments are unlikely to be distributed through society in the same way. Optimisation of protection may thus introduce a substantial inequity between one individual and another. This inequity can be limited by incorporating source-related restrictions on individual dose into the process of optimization. The Commission calls these source-related dose constraints, previously called upper bounds. They form an integral part of the optimization of protection. For potential exposures, the corresponding concept is the risk constraint' (ICRP, 1991).

This statement continues to be the Commission's view.

(226) For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public could receive from the planned operation of any controlled source.

5.9.2. Reference levels

(227) In emergency or existing controllable exposure situations, the reference levels represent the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.

(228) Once protective actions have been implemented through optimisation subject to reference levels, doses can be measured or assessed to workers and members of the public. The reference level is then used as a benchmark against which protection options can be judged retrospectively. The distribution of doses that has resulted from the implementation of a planned protective strategy may or may not include exposures above the reference level. Efforts should be aimed at reducing any exposures that are above the reference level to a level that is below, if possible. While resource allocation should focus on those exposures above the reference level, it should not be forgotten that optimised protection should be applied to all exposed individuals, whether their exposure is above or below the reference level.

(229) Protection is optimised with reference to a specific situation. Should exposure conditions evolve with time, as in the case of an emergency situation for example, the applicable reference level should be revisited to see whether the selected values continue to address protection needs.

5.9.3. Factors influencing the choice of source-related dose constraints and reference levels

(230) In providing guidance on values for dose constraints and reference levels, the Commission has assumed a linear relationship between radiation dose and risk of cancer in exposed organs or tissues or hereditary effects. The Commission considers that, for the purposes of radiological protection, the assumption of linearity applies up to acute or annual doses of about 100 mSv. At higher doses, there is an increased likelihood of tissue injuries and a significant risk of stochastic effects. For these reasons, the Commission considers that the maximum value for a reference level is 100 mSv incurred either acutely or in a year, although reference levels this high would only be established under extreme (unavoidable) circumstances. There is no net individual or societal benefit that can compensate for higher levels of exposures, except in exceptional situations such as the saving of life or the prevention of a serious disaster.

(231) Many of the numerical criteria recommended by the Commission in *Publication 60* and subsequent publications can be, with the exception of the limits, regarded as constraints or reference levels. The values fall into three defined bands (see Table 5) with the attributes described in the following paragraphs. The

Commission considers that it is useful to present these values in this manner as it enables selection of an appropriate value for a constraint or a reference level for a specific situation that has not been addressed explicitly by the Commission. The values are expressed in terms of projected incremental doses (mSv in a year).

(232) The first band, less than 1 mSv, applies to situations where individuals receive exposures – usually planned – that are of no direct benefit to them but there is a benefit to society. The exposure of members of the public from the planned operation of practices is a prime example of this type of situation. Constraints and reference levels in this band would be selected for situations where there is general information and environmental surveillance or monitoring or assessment and where individuals may receive information but no training. The corresponding doses would represent a marginal increase above the natural background and are at least two orders of magnitude lower than the maximum value for a reference level, thus providing a rigorous level of protection.

(233) The second band, from 1 mSv to 20 mSv, applies in circumstances where individuals receive direct benefits from an exposure situation but not necessarily from the exposure, or the source of the exposure, itself. Constraints and reference levels in this band will often be set in circumstances where there is individual surveillance or dose monitoring or assessment, and where individuals benefit from training or information. Examples are the constraints set for occupational exposure in planned situations. Exposure situations involving abnormally high levels of natural background radiation may also be in this band.

(234) The third band, from 20 mSv to 100 mSv, applies in unusual, and often, extreme situations where actions taken to reduce exposures would be disruptive or where the source cannot be controlled. Reference levels and, occasionally, constraints could also be set in this range in circumstances where benefits from the exposure situation are commensurately high. Action taken to reduce exposures in a radiological emergency is the main example of this type of situation. The Commission's upper value for a reference level of 100 mSv is set so as to restrict or avoid the probability of significant health effects and, as such, should be considered to apply to the total dose to an individual from all sources. In most such instances one source will be dominant and the upper value could be applied to that source.

(235) The Commission's banding of constraints and reference levels applies across all three exposure situations and refers to the projected dose over a time period that is appropriate for the situation under consideration. In the case of the continuing exposures in both planned and existing exposure situations, the values refer to the additional dose conventionally expressed as dose per year. For emergency situations, the values refer to acute exposures, which would not be expected to be repeated.

(236) In emergency and existing exposure situations, it could be argued that the source-related restriction would not provide sufficient protection where there are multiple sources. Generally, however, there is a dominant source and the selection of the appropriate reference level ensures the required level of protection. The Commission still considers that the source-related principle of optimisation below the constraint or reference level is the most effective tool for protection, whatever the situation.

(237) A necessary stage in applying the principle of optimisation of protection is the selection of an appropriate value for the dose constraint or the reference level. The relevant national authorities will often play a major role in this process. The first step is to characterise the relevant exposure situation in terms of the nature of the exposure, the benefits from the exposure situation to individuals and society, and the practicability of reducing or preventing the exposures. Comparison of these attributes with the characteristics described in Table 5 should enable the selection of the appropriate band for the constraint or the reference level. The specific value for the constraint may then be established by a process of generic optimisation that takes account of national or regional attributes and preferences together, where appropriate, with a consideration of international guidance and good practice elsewhere. The Commission provides additional guidance below on the selection of constraints and reference levels for occupational, medical and public exposure in the three exposure situations.

Table 5. Framework for source-related dose constraints and reference levels with examples of constraints for workers and the public from single dominant sources for all situations that can be controlled (effective dose in a year).

Bands of Projected Effective Dose[1] (mSv)	Characteristics of the Situation	Radiological Protection Requirements	Examples
20 to 100	Individuals exposed by sources that are either not controllable or where actions to reduce doses would be disproportionately disruptive. Exposures are usually controlled by action on the exposure pathways. Individuals may or may not receive benefit from the exposure situations.	Consideration should be given to reducing doses. Increasing efforts should be made to reduce doses as they approach 100 mSv. Individuals should receive information on radiation risk and on the actions to reduce doses. Assessment of individual doses should be undertaken.	Reference level for evacuation in a radiological emergency.
1 to 20	Individuals will usually receive direct benefit from the exposure situation but not necessarily from the exposure itself. Exposures may be controlled at source or, alternatively, by action in the exposure pathways.	Where possible, general information should be made available to enable individuals to reduce their doses. For planned situations, individual monitoring and training should take place.	Constraints set for occupational exposure in planned situations. Reference level for radon in dwellings.
0.01 to 1	Individuals are exposed to a source that gives them no direct benefit but benefits society in general. Exposures are usually controlled by action taken directly on the source for which radiological protection requirements can be planned in advance.	General information on the level of exposure should be made available. Periodic checks should be made on the exposure pathways as to the level of exposure.	Constraints set for public exposure in planned situations.

[1] Acute or annual dose.