Considerations

on the

Concept of Dose Constraint

A Report by

a Joint Group of Experts
from
the OECD Nuclear Energy Agency
and
the European Commission

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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- *developing exchanges of scientific and technical information particularly through participation in common services;*
- *setting up international research and development programmes and joint undertakings.*

In these and related tasks, NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has concluded a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

During the discussions carried out internationally for the preparation of the FAO/IAEA/ILO/NEA(OECD)/PAHO/WHO *Basic Safety Standards for Protection Against Ionising Radiation and the Safety of Radiation Sources* (BSS) and of the European Union *Basic Safety Standards for the Protection of the Health of Workers and the General Public Against the Danger Arising from Ionising Radiation (EURATOM Directives)*, it appeared that the concept of dose constraint was far from enjoying full understanding and homogenous interpretation of its meaning and application in the regulatory and operational domains.

The NEA Committee on Radiation Protection and Public Health (CRPPH), therefore, decided, in 1993, to set up an Expert Group to deal with this matter. In view of a similar exercise simultaneously launched by the European Commission (EC) Group of experts referred to in Article 31 of the *Euratom Treaty*, it was also decided that the Expert Group on Dose Constraints should be jointly sponsored by the two organisations. The objective of the Joint NEA/EC Expert Group was to review and elaborate the concept of dose constraint and its links with the various levels which are used in practical radiation protection.

The report of the Joint Expert Group is submitted as a contribution to the international debate on the issue of dose constraints and is intended to assist national authorities and international organisations in their activities in the area of optimisation of protection.

This report, which represents the views of the Joint Expert Group, is published by the OECD Nuclear Energy Agency by arrangement with the European Commission. This publication is issued under the responsibility of the Secretary-General of the OECD and does not commit Member countries.

The report was prepared by the following experts designated by the NEA CRPPH and the EC Group of experts referred to in Article 31 of the Euratom Treaty:

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INTRODUCTION

The *1990 Recommendations* of the International Commission on Radiological Protection (ICRP Publication 60) propose a system of protection based on the three principles of *justification* of a practice or an intervention, *optimisation* of protection and *limitation* of individual dose/risk.

The concept of "dose constraint" was explicitly introduced in ICRP Publication 60 within the context of optimisation of protection. This concept, however, is not new and its introduction corresponds, rather, to an attempt to consolidate and rationalise a variety of concepts that already existed in previous ICRP guidance.

Moreover, when the phase of protection planning for a source or practice or task is terminated and the operational phase is started, it is appropriate to establish some practical levels corresponding to values of measurable quantities above which some specific action or decision is expected to be taken.

This report discusses the meaning, the role and the scope of application of the concept of dose constraint for different types of practices and exposure situations. In this context, the report also discusses the relations of this concept with the concepts of "dose limits" and "dose upperbounds" and considers how the regulatory use of the dose limits is affected by the introduction of dose constraints into the system of protection. The report then examines the meaning and the function of the various levels used in practical radiation protection and their application to the cases of occupational exposures, public exposures and medical exposures.

The terminology used in this report was extensively discussed within the Expert Group. There is, in fact, no internationally agreed system of definitions for the different types of limits and levels used in regulation and in practical radiation protection. Particular attention was payed to the need to avoid the use of the term "limit" for quantities other than the basic individual limits expressed as dose limits in ICRP Publication 60 and in international standards such as the *Basic Safety Standards for Protection Against Ionising Radiation and the Safety of Radiation Sources* (BSS) and the *Basic Safety Standards for the Protection of the Health of Workers and the General Public Against the Danger Arising from Ionising Radiation (Euratom Directives)*. This is why the Expert Group decided to define the other levels used in practical radiation protection in support of dose

limits and dose constraints as, respectively, "authorised levels" for those having a regulatory meaning and "operational levels" for those used in the day-to-day radiation protection work.

Finally, it is to be noted that the Expert Group did not intend to express a definitive position on these concepts nor to give recommendations on their interpretation, establishment and use. This report is, therefore, to be seen as a reflection of the views of the Expert Group on this subject, which are submitted as a contribution to the international debate in this area.

DOSE CONSTRAINTS

As mentioned before, the concept of dose constraint is not completely new, but is rather the result of the consolidation and rationalisation of some concepts which had been progressively introduced in previous ICRP guidance.

The Development of the Concept of Dose Constraint

Prior to the issue of ICRP Publication 26, in 1977, the primary aim of the Commission's recommendations was to protect the individual and, therefore, the emphasis was put on the person-related "maximum permissible dose", which later evolved into the concept of "dose limit". This concept had, at the same time, a *prospective* meaning (for planning of protection in a practice) and a *retrospective* meaning (for demonstration of compliance with statutory limits).

Progressively, compliance with the dose limits was no longer considered sufficient and the concept of optimisation of protection began to be introduced, initially in ICRP Publication 22, of 1973, and, then, more formally, in ICRP Publication 26. This implied the introduction of the approach of source-related assessments and protection, and the need to introduce limitations to the dose to individuals from a given source. In this context, the concern was raised that the distributions of benefits and detriments considered and compared in the optimisation process are not usually the same in a group of persons. This may create inequity in that the combination of these distributions corresponding to the optimum collective benefit could result in doses to some individuals which are not acceptable.

It was, therefore, felt that a distribution of benefits could be used in an optimisation assessment to justify a distribution of detriments only if the detriment to each individual is limited to some maximum value regarded as acceptable by society. The concept of constraint to optimisation, although not yet its name, was, therefore, already included in the *1977 Recommendations* of the ICRP. At that

time, however, the value of the dose limit was seen as the only constraint to optimisation.

ICRP Publication 60 redefined the concept of dose limit as the lower boundary to unacceptable risk. With this definition, the dose limit no longer could be seen to provide an adequate restriction on the possible inequity in the distribution of individual doses resulting from the process of optimisation of protection. The concept of "dose constraint" was, therefore, explicitly introduced. By analogy, a concept of risk constraint was also introduced in ICRP Publication 60 in the area of control of the so called "potential exposures".

The principle of optimisation of protection is formulated as follows by the ICRP (Publication 60, para. 112):

> 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 procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risk to individuals in the case of potential exposures (risks constraints), so as to limit the inequity likely to result from the inherent economic and social judgements.

Hence, it appears clear that the concept of source-related dose constraints applies to the optimisation of protection *for practices*, in which the source is controllable, but *not for interventions* in situations such as, for example, exposure after an accident.

Potential exposures are those which may or may not occur. The probability of occurrence and the magnitude of its consequences have to be considered. However, work in this area is still in its early stages and only general guidance has been developed so far. In contrast to dose limits, no risk limits are recommended. It is not yet clear how risk constraints as mentioned in the ICRP principle of optimisation will be used, since there are great difficulties in defining procedures for the optimisation of protection against potential exposures. Therefore, in this paper, risk constraints are not discussed.

General Application of Dose Constraints in the Optimisation Process

Meaning of Dose Constraints

The objective of a dose constraint is to be a ceiling to the values of individual doses from a source, practice or task which could be determined to be acceptable in the process of optimisation of protection for that source, practice or task. In other words, a dose constraint is the value of individual dose that is

expected not to be exceeded in the predicted individual dose distribution resulting from the optimisation process.

The use of dose constraints is *prospective*, being applied in the planning of protection in all situations where optimisation of protection is involved (e.g., in the design or modifications of plants, in the preparation of an operation, etc.). Although the dose constraint is expressed in terms of individual dose, it is a source-related quantity which refers to the source, practice or task to which the optimisation process is being applied.

Once the optimisation under constraint is made, the constraint ceases to be operationally relevant and the optimised protection option will result in the choice of a level of dose and/or a derived quantity to be used as the actual target for operation. The design features and the operational performance are meant to be judged against this target which has, therefore, a *retrospective* character.

The Role of Dose Constraints in the Optimisation Process

The dose constraint may be related to the protection of persons against exposures from a complete practice or from any part of a practice which is subject to optimisation, that is, exposures due to:

- a source such as a simple small one, a single machine, or a big installation;
- a set of sources in an installation;
- a particular task in connection with a source or set of sources, or a complete job, such as a specified maintenance task, or a group of operations in a specific type of industry.

In each case, those who establish constraints must clearly describe the relevant source, and the magnitude of the constraint selected should be appropriate to the purpose in hand.

A design or work procedure involving exposure of workers or members of the public to radiation will give rise to a distribution of doses, and therefore of detriment, and usually to a different distribution of benefits. Thus, the dose constraint, as ceiling on the predicted individual doses in the dose distributions resulting from the different options considered during the optimisation process, is meant to be used to restrict the inequity likely to result from the above-mentioned difference of detriment and benefit distributions within the populations concerned.

In addition to the inequity due to different distributions of benefits and detriments from one source, practice or task, another kind of inequity may result from practices of a same or similar kind being characterised by different levels of

protection, whereby a practice might give rise to higher individual (and perhaps collective) doses than a comparable practice. If the experience from well managed operations shows that a given level of protection is practically achieved, there are no *a priori* reasons to accept for a similar practice individual doses higher than those achieved by the above-mentioned operations. This consistency of protection levels between the two similar practices can be achieved by an appropriate choice of the dose constraint.

On the basis of these considerations, the choice of the value of the dose constraint for a given source, practice or task can result from one or a combination of the following approaches:

- the use of the result of a generic optimisation of protection for the source, practice or task being considered,
- the use of the experience of well managed operation of practices or sources of the same kind.

It should be stressed again that the application of dose constraints puts emphasis on individual doses in the optimisation of protection. Restrictions on collective dose per unit practice, which are used in some countries in terms of person-Sv/GWa for nuclear power generation or of collective dose per task (e.g., for fuel reloading in a nuclear power plant), are not dose constraints as discussed here. Such restrictions may be useful, and are indeed used in certain countries to reduce the total and the average exposure of a group of workers.

Because, as it was already said, the dose constraint is a ceiling to the predicted individual doses in the optimisation, the actual optimisation process has to be carried out in the region of individual doses below the dose constraint. Protection options resulting in individual dose distributions which include values exceeding the dose constraint should be eliminated from the optimisation process, which will continue to be applied among the remaining options. However, there may be cases where no additional efforts for optimisation need to be made after setting a dose constraint. Particularly for simple sources this might be a justified approach.

Dose Constraint and Dose Limit

It is important to recognise that the dose constraint should not be confused with the dose limit, which is a person-related quantity having the statute of a legal limit to the dose that an individual could receive from the whole of practices to which he/she can be exposed at present and in the foreseeable future.

The evolution from individual-related to source-related protection linked with the formal introduction of optimisation in the 1970s gave rise to the concern that

the combination of exposures from several sources to the same individual could exceed the dose limit. This concern particularly referred to the exposure of members of the public from multiple sources. The response to this was the proposal, developed during the 1980s, that the exposure of individuals from each given source should be limited by a fraction of the dose limit (called in the past "source-related dose upperbound") such that the sum of the contributions of the exposure of those individuals from several sources could not exceed the dose limit. This apportionment of the limit belongs to the principle of limitation of individual doses and is conceptually different from the establishment of constraints for the optimisation of given sources. In selecting a constraint the existence of a source upperbound should be taken into account such that the numerical values of the constraints should be less than or at most equal to that of the source upperbound.

Quantities for Constraints

Primarily the dose constraint is expressed as individual dose. In the case of public exposure, this is the mean dose to the critical group for the source or practice considered. It may also be expressed in terms of corresponding derived operational quantities, such as annual radioactive emission from a nuclear installation, exposure rate from a radiation device, etc. For these values the general term "derived constraint" is recommended.

Realistic exposure models and assumptions on exposure pathways should be used for the establishment of the derived constraints as for the optimisation process. However, derived constraints may also be established directly by investigating the experience from well managed operations.

AUTHORISED LEVELS AND OPERATIONAL LEVELS

As it was mentioned in the Introduction, authorised levels and operational levels are values of measured or assessed quantities which, if exceeded in the operation of a practice, require some specific action or decision to be taken. They are established as a result of optimisation and, in view of their retrospective use, are conceptually different from the (prospective) dose constraints. Authorised levels have always regulatory significance, while operational levels may or may not correspond to regulatory requirements.

These levels can be expressed in terms of doses or dose rates, but more often in terms of derived quantities (intensity of radiation field, activity concentration, etc.). They can be of the following types:

a) *Authorised levels* – concerning operation indicators, for example effluent discharge levels proposed by the operator/licensee and authorised by the licensing authorities, or directly established by the regulatory authorities. They are usually attached to an authorisation as technical prescriptions and are essentially used as checkpoints to assess compliance with established restrictions on operation.

   In view of the fact that the authorised levels are fixed on the basis of the results of optimisation of protection, taking into account past experience from well managed operations, their numerical values are expected to correspond to an individual dose lower than, and at most equal to, the numerical value of the dose constraint.

b) *Operational levels* – related to specific parameters or quantities often established by the management as internal restrictions for the proper conduct of operations or as a warning of deteriorating operational conditions, if they are exceeded. Operational levels are expected to be normally lower than the corresponding authorised levels.

A frequently used example of operational level is the "investigation level". Exceeding an investigation level should trigger one or more of the following actions:

- enhanced attention and monitoring of trends;
- investigation on the causes and the evolution of the events leading to the exceeding of the investigation level;
- consideration and implementation of corrective actions;
- reporting to the management and the regulatory authorities as appropriate.

The value of an investigation level can be established in the following ways:

- as a fraction of an authorised level, as warning threshold against approaching or exceeding that level; *or*
- as a multiple of a normal operational value (lower than or equal to the corresponding authorised level) to indicate a deviation or a trend deviating from normal conditions.

THE APPLICATION OF CONSTRAINTS

This section deals with dose constraints, authorised levels and operational levels as they are applied to occupational, public, and medical exposures.

Constraints may help the management of a licensee, operator or employer in optimising protection in design or in planning operations. Regulators may use it in

a generic way for categories of similar sources, practices or tasks, or specifically in licensing individual sources, practices or tasks. The establishment of constraints should be the result of an interaction between operators and regulators.

Although constraints can be established from a review of experience from well managed operations in comparable practices, or from a generic optimisation, the final choice of the protection option may also be affected by political, social, or other reasons suggesting the need not to exceed a given level of individual dose. The need for trade-offs between different exposure situations, for example between public exposure and occupational exposure, may also be a factor in the choice of constraints. For example, a public dose constraint which is too restrictive may also have a negative impact on occupational exposures.

Once a protection option has been selected by optimisation, the constraint ceases to be relevant unless and until there is a reoptimisation leading to the choice of a new protection option. This reselection may be required by changes of operating conditions, new technical advancements, new economical or social situations, or by finding that individual doses do often exceed an operational level.

One of the approaches to setting constraints is to refer to the experience resulting from "good practices". In order to facilitate this, the bodies in charge of past-experience analysis should draw up "handbooks of good practice" reflecting the state of the art at a given time for the various types of sources or practices. A typical example is the *Manual of Good Practice in Work Management,* currently being published by the NEA.

The introduction of constraints will certainly encourage the development of databases of past experience and the improvement of operational dosimetry related to special tasks or sources. It is probable, in fact, that one of the major side-effects of the introduction of the concept of constraints will be to force authorities and operators to analyse the feedback of experience in order to avoid setting arbitrary values for constraints. This is one of the ways in which the constraints can contribute to the dialogue between operators and authorities.

It is to be noted, however, that the simple act of compiling statistical data on individual doses or other relevant data is not sufficient for building up useful past-experience databases to be used in setting constraints. A *sine qua non* condition is the identification of links between these databases and the different types of sources, practices or tasks. For this purpose, the database of individual annual doses should be completed by a systematic review of past experience including data on overall performance (e.g., collective doses), operating characteristics (such as dose rates or exposure times) and protective measures adopted.

Once a practice, task or operation has been optimised below the pre-established constraints, levels of the types defined on pages 12-13 can be set by the regulators, licensees, and operators as yardsticks retrospectively used to check compliance with the performance expected from the optimised protection option.

It is to be noted that the establishment by regulators of generic constraints and reference levels for a given category of sources or plants should be made taking account of the possible coexistence of new facilities with existing facilities for which the protection options were designed according to an earlier standard.

Occupational Exposure

Dose constraints for occupational exposure may be set for the dose to an individual from a particular source of exposure, from a complete job, such as a specified maintenance task, or from a group of operations in a specific type of industry. The constraint can be expressed as a single dose or as a dose over a given time period.

Due to the variability of exposures in different fields of application of ionising radiation and nuclear energy, the establishment of a generic constraint for workers is not practicable. For example, in medical radiology usually the constraints may be very low. However, in some underground mines or in case of special maintenance operations or decontamination activities in a nuclear power plant high exposures cannot easily be diminished. Usually, however, dose constraints for occupational exposure can be set at levels significantly lower than the relevant dose limit.

Where workers are employed exclusively in one group of operations, there is no problem in applying the constraint to the doses received from these operations. Thus single dose constraints could be applied, for example, to the optimisation of protection of workers in a diagnostic X-ray department. Different constraints could be applied to the optimisation of protection of workers in external radiotherapy or in brachytherapy. In principle, there is no change in this position if some people work for part of their time in one department and part in another.

In the context of exposure of workers, the experience with well managed operations is of particular importance in setting constraints. National inquiries or international databases like the NEA/OECD Information System on Occupational Exposure (ISOE) deliver a large amount of experience with exposures related to specific operations in nuclear power plants which can be used in establishing constraints.

The importance of the commitment of management to optimisation of protection is to be emphasised. The management should be involved in the setting

of dose constraints for specified operations and tasks in consultation with the worker representatives and safety committees and, as appropriate, with the agreement of the regulatory body. The constraints, and the corresponding choice of optimised options, should be periodically reviewed in the light of what has been achieved and any changes in circumstances.

One of the major concerns in occupational radiation protection is that of transient workers, such as contractors for maintenance operations in nuclear power plants, who do not belong to the staff of the licensee[1]. Source-related dose constraints can be established for well defined tasks, but this may not be sufficient to prevent transient workers from exceeding the dose limits, even if this may contribute to keep doses as low as is reasonably achievable. To address this situation, co-operation of employers and licensees will be necessary, in addition to the establishment of constraints, to overcome the difficulties of optimisation of protection for operations involving transient workers. This should include the establishment of specific operational levels to prevent these workers from being systematically exposed to dose levels close to the dose limits.

The doses actually received by workers should be subject to retrospective scrutiny to check that individual doses are as low as reasonably achievable. The concept of investigation level is of use in this context. These levels may relate to doses received by individuals involved in a particular operation or to doses received by individuals within a place of work. If an investigation level is exceeded, there should be an investigation of the circumstances which led to the exposure, to determine whether doses were as low as reasonably achievable, and a review of the operating arrangements.

Investigation levels, in terms of dose rate or activity concentrations in the working environment, may be useful to check that there is no deterioration in working conditions. They may also play an important role in review of experience and feedback for future optimisation. Regulatory authorities may wish to set an overall investigation level that applies to the totality of an individual's exposure. This would require a regulatory system for collation of dose information on a national basis.

Public Exposure

According to the ICRP, for public exposure the constraints are more important than the limits. With the widespread use of source-related constraints and specific restrictions on sources, public exposures are generally much lower than the dose limits. However, because the constraint on a source or practice is

[1] The European Directive 89/618/Euratom is specifically designed to address this issue.

source-related, it might, at least in principle, fail to take adequate account of the exposures from other sources or practices, at present and in the future. Regulatory authorities should take this into account when setting dose constraints for the public which, in fact, should never be as high as the value of the dose limit.

In practice, almost all public exposure is controlled by the procedures of constrained optimisation and the use of authorised levels. It is often convenient to class together individuals who form a homogeneous group with respect to their exposures to a single source. When such a group is typical of those most highly exposed by that source, it is known as a "critical group". The dose constraint should be applied to the mean dose in the critical group from the source for which the protection is being optimised. This group may also incur doses from other sources. If the exposures to the members of any critical group are likely to approach the dose limit for public exposure, the constraints applied to each source should be selected to allow for any significant contribution from other sources to the exposure of the critical group. This may be done by ensuring that the dose constraint for each source is lower than or, at least, does not exceed the fraction of the dose limit ("dose upperbound") allocated to that source. Criteria for the establishment of the constraints for members of the public are suggested in IAEA TECDOC-664.

Dose constraints generally apply to the dose from all exposure pathways affecting a given critical group. In some cases it may be appropriate to use constraints for particular exposure pathways. One could, for example, set a constraint for the exposure of members of the public to liquid releases from a nuclear installation. For the airborne releases another constraint may be applicable. These different pathway-specific constraints would be the ceilings to the optimisation process applied, respectively, to liquid and to airborne effluent treatment systems.

In the case of discharges of radioactive material into the environment, the regulatory authorities set authorised levels of discharge which should result from the application of the optimisation process to the source in question. These authorised levels are generally set in terms of annual discharge rates, but also in terms of *pro rata* fractions of the annual level for shorter time periods. It might then be appropriate to set an investigation level at some fraction of the authorised level of discharge. If the investigation level is exceeded, a review of the circumstances that led to this situation is warranted to make sure that future discharges will not exceed relevant authorised or operational levels.

Medical exposure

Medical exposure is the exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly and willingly helping in the support of patients; and by volunteers in a programme of biomedical research involving their exposure. The concept of dose constraint applies in a different way to patients and to the other types of medical exposure.

Patient Exposure

Optimisation of protection should be applied to the planning of protection provisions in diagnostic and therapeutic practices involving radiation exposure of patients. In this case, the justification of procedures causing medical exposure is a matter for medical judgement, but it is to be expected that the corresponding benefit is directly enjoyed by the exposed patients, or, in special cases, by society.

In this case, the concept of dose limit does not apply, but the concept of dose constraint in principle does apply. However, the practical implementation of this concept is difficult, because of the need to allow for the possibility of exceeding a constraint for a single patient if desired diagnostic information or therapeutic effect is otherwise not achievable. Therefore, the constraints in the optimisation of medical procedures on patients should not be seen as rigid upper boundaries to the process of optimisation, but should rather have the meaning of "medical reference levels" selected by appropriate bodies using national and international experience from well managed operations, or using generic optimisation, as appropriate.

For medical exposures in diagnostic radiology and diagnostic nuclear medicine medical reference levels have rather the function of investigation levels. An internal investigation should be carried out by a medical department if the average dose assessed for a standard-size patient, for a specific type of examination, was found repeatedly and significantly to exceed the relevant medical reference level. Unless this is justified by a sound medical judgement, appropriate steps should be taken by the department to improve practice; this would involve changes in technique or equipment to reduce doses below the medical reference level without compromising the quality of diagnostic information[2].

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[2] In the FAO/IAEA/ILO/NEA(OECD)/PAHO/WHO *Basic Safety Standards*, "guidance levels" for medical exposure are recommended that have a slightly different meaning. They are defined as levels of a specified quantity above which appropriate actions should be considered. In some circumstances, actions may also need to be considered when the specified quantity is substantially below the guidance level.

The way of restricting exposures to patients is mainly through quality assurance, including quality control of the medical devices, optimised procedures and appropriate training and education of medical personnel.

In the case of radiation therapy, medical reference levels cannot be established. The optimal dose, both in the target and non-target tissues, should be determined individually.

Other medical exposures

There are other types of exposure which fall into the category of medical exposure. The exposure of volunteers in scientific and clinical research has to be limited by constraints as real boundaries to optimisation, as opposed to medical reference levels. In the special case of patients who voluntarily accept to undergo an experimental diagnostic or therapy procedure, dose constraints should be established case by case.

Another category of medical exposure refers to the exposure of relatives and other non-occupationally exposed persons who help and comfort patients during examinations or therapy in hospital or when they are released from the hospital after a radionuclide therapy. Although the application of constraints may be useful for the planning of protection in these situations, these levels should be applied flexibly and cautiously depending on what is considered to be of importance for the welfare of the patient. It should be possible to exceed a constraint in these cases after confirmation that from a medical point of view a net benefit arises. Values of dose constraints for these situations are recommended in the FAO/IAEA/ILO/NEA(OECD)/PAHO/WHO *Basic Safety Standards*.

FINAL REMARKS

Dose constraints may be a useful tool for improving optimisation in practical radiation protection. The dose constraints should not be misinterpreted and misused as a new category of limits. Moreover, the new concept has to be applied with common sense to avoid danger of over-sophistication in radiation protection leading to an inflation of terms and concepts of difficult application in practical day-to-day work.

At the present stage in the implementation of optimisation of radiation protection, the application of such an approach remains limited, although there are examples of concrete applications in some countries, including sometimes the use of constraints. In many sectors, especially in industry and the medical domain, a structured optimisation approach, which explicitly takes into account economic and social considerations, has not yet been widely adopted. One of the reasons for

this fact is that the economic and social criteria which are used in the optimisation process are largely dependent on value judgements, for which no consensus exists. In view of this situation, referring to good practice currently seems to be the most suitable approach for setting dose constraints.

In practical terms, the effectiveness of dose constraints depends on their adequate matching to the sources. In this context, the operators and people responsible for the sources are still in the best position to set or propose dose constraints. From a regulatory perspective, dose constraints appear to be a useful tool for influencing the quality of radiological protection, as well as a vector for discussion between the authorities and operators, to ensure effective application of the optimisation principle.

It is important to note that the introduction of a constraint should not be seen as a means to avoid the further improvement of protection that can be achieved by a full application of the optimisation process. The proper use of authorised levels and operational levels may provide an effective support to implement the results of the optimisation process.

This paper is intended to contribute to the general discussion of the concept of constraint and the applicability of this concept in radiation protection. Practical guidance for establishing numerical values of constraints is left to other international organisations in their respective areas of competence.

FURTHER READING

1. ICRP, "Recommendations That Doses Be Kept as Low as Readily Achievable", ICRP Publication 22, Pergamon Press, 1973.
2. ICRP, "Recommendations of the ICRP", ICRP Publication 26, Pergamon Press, 1977.
3. ICRP, "Cost Benefit Analysis in the Optimisation of Radiation Protection", ICRP Publication 37, Pergamon Press, 1983.
4. IAEA,"Principles for Limiting Releases of Radioactive Effluent, into the Environment", *Safety Series*, No. 77, Vienna, 1986.
5. IAEA,"Principles for the Establishment of Upper Bounds to Doses to Individuals from Global and Regional Sources", *Safety Series*, No. 92, Vienna, 1989.
6. ICRP, "Optimisation and Decision - Making in Radiological Protection", ICRP Publication 55, Pergamon Press, 1989.
7. ICRP, "1990 Recommendations of the International Commission on Radiological Protection", ICRP Publication 60, Pergamon Press, 1991.
8. H.J. Dunster, "The Use of Constraints by ICRP", *Journal of Radiological Protection*, **12**:219, 1992.
9. IAEA,"Establishment of Source Related Dose Constraints for Members of the Public", TECDOC-664, Vienna, 1992.
10. NRPB, "Board Statement on the 1990 Recommendations of ICRP", *Documents of the NRPB*, **4**(1), 1993.
11. NRPB, "Occupational, Public and Medical Exposure", *Documents of the NRPB*, **4**(2), 1993.
12. A. Sugier *et al.*, "Source Related Dose Constraints", *Proceedings of International Congress "Harmonization in Radiation Protection: from Theory to Practical Applications", Taormina, Italy, 10-13 October 1993.* J. Lochard *et al.*, "The Concept of Dose Constraint", DG XI. 93-ET-016, 1994.
13. OECD/NEA, "Good Practice in Work Management", in press.

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