INTERNATIONAL RADIATION PROTECTION ASSOCIATION

IRPA Member Societies' Contributions to the Development of new ICRP Recommendations

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1. Background

In the autumn 1999 the International Radiation Protection Association (IRPA) invited its member Societies to comment on Professor Roger Clarke's 'Controllable Dose' paper and subsequent article "Control of Low Level Radiation Exposure: Time for a Change?" which was published in the Journal of Radiation Protection Vol. 19 No. 2, 107-225 (1999). It was considered that such a review undertaken by the radiation protection practitioner community would provide a timely stock take of the effectiveness of the current framework for radiological protection, and provide important input to ICRP's early deliberations on new or revised recommendations for the future.

The IRPA 10 Congress formed the obvious focus for bringing together the response from the various Societies. Many Societies had formed working groups or undertaken member consultation exercises, in order to develop a view on the Clarke paper. In the interim, the debate had continued with Professor Clarke participating in a number of prestigious meetings and bodies such as NEA-CRPPH publishing related reports or commentaries. The collection of replies from the Societies presented in this report, and the summary below therefore, represent an unreconstructed view of the Clarke article and do not necessarily take account of some of the most recent developments in the thinking of the author or the evolution of the "new" philosophy.

The report includes those written comments from Societies made available to IRPA and/or presented at IRPA 10 up to now. ICRP may receive direct comments from Societies or individual radiation protection practitioners. IRPA has made no attempt to process or to analyse the Society responses and the following summary which largely follows the highlight report to IRPA 10, seeks only to draw attention to some of the main themes emerging from the contributions and discussions at the Congress.

2. Summary

Although it was not the intention of the IRPA 10 session to reach any consensus, nonetheless some early common themes emerged from the papers and discussions.

- The process and mechanisms for engaging the protection community through IRPA and the societies in the review of new ICRP proposals were universally welcomed and applauded.

- The basic principles of justification, optimisation and dose limitation have proved sound. Hence in any ICRP review, it was necessary first to concentrate on rectifying defects or weaknesses in the present system before introducing more radical changes or even a new system of protection. In making such changes it would be important to take account of the benefits and the costs of change.

- While the current system for radiation protection may be viewed as complex and difficult to explain to and reconcile with lay audiences, it is important to differentiate between what can sensibly and reasonably be simplified and what is actually a presentational and communications problem. These two require different solutions and the involvement of different mix of experts in researching and developing these solutions.

- A unified and fully integrated system for radiation protection while laudable may only seek to further complicate and confuse. It may be necessary to acknowledge that a limited number of activities eg., radiotherapy, while satisfying certain core RP criteria, will be better dealt with by a series of application specific, risk management recommendations and guidelines. The current system allows for differing regimes for different types of exposure situations. These flow directly from the varying risk and exposure management requirements effective in each category of exposure.

- As far as possible any RP framework should be robust to thinking on dose-effect relationships. In significant areas of radiation protection practice, the resolution of the LNT debate will not radically alter standards or requirements for protection. It is important to separate out the underpinning science and the associated limitations, and the risk management aims and objectives. This should be first and foremost a framework for responsible risk management and risk control.

- In several areas of the present system, eg., justification, optimisation and quantified risk assessment and collective dose, the fundamentals were appropriate, but there is still a lack of clear interpretation as to how they are to be applied in practice, in a manner that is transparent and acceptable to practitioners, workers, and the public. If the framework is considered to be a compendium of indicators and tools, then these need to come with full instructions as to the proper and appropriate use. ICRP could help in this, but it is also a matter for organisations including IRPA, IAEA, and NEA. There is a need too to place RP in the context of other occupational risks.

- Other stakeholders including professionals, interest groups and the public, need to be brought into the debate. Professionals are cautioned that they too often assumed knowledge of what concerned and confused the public and other non-specialist groups without checking these assumptions. The mechanisms for wider consultation and involvement need to be developed and the role of IRPA and societies in these clarified.

- It will be necessary to address in its own right protection of the environment, including biota, in the new system but much work needs to be done before this can be achieved. Important lessons can be learnt from other areas eg., chemicals, where protection of the environment is further developed than for radiations.

- Great care is necessary with language, terminology and concepts, especially in not introducing new definitions unless they are absolutely necessary. Allied to this, is the need for early commitment to an effective communications strategy with both the RP community and other stakeholders with the aim of achieving widescale engagement in and ownership of the evolving protection framework.

- More thinking and development are needed on the way in which quantities such as collective dose, "trivial" dose and concepts such as referencing dose/exposures to background levels, action levels and ALARA/ALARP are to be understood and used in the new system. In particular, the logic and mechanisms for wholesale abandonment of collective dose, for pre-setting a trivial dose level and replacing dose limits with action and investigation levels, are not apparent.

- Whatever revisions to the current system are proposed, these should be carefully "road tested" for their application before being firmly adopted.

- The continued involvement of the RP practitioners in the development of ICRP thinking is strongly advocated, and the next version of the proposals is eagerly awaited.

3. Contribution of the Nordic Radiation Protection Society

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INTRODUCTION

The present ICRP recommendations were developed over several decades. They have changed during this time mainly for two reasons:

- increased knowledge on the effects of ionising radiation, and
- additional sources requiring new target groups to be protected

Thus the changes can be characterised as ”further development of the system”.

In order to make the recommendations practicable a number of approximations and simplifications were adopted because of lack of radiobiological knowledge and the complexity of issues. Practicability of recommendations also requires them to be stable, because the time required for adopting and translating them to a legal instrument in the countries has shown to be of the order of a decade.

The present chairman of the ICRP, Professor Roger Clarke asks in his article (1) whether it is time for a change regarding the control of low level radiation exposure. He takes up the criticisms against the ICRP approach as arguments for a change, *e.g.*:

- disputes among scientists on the validity of Linear-Non-Threshold-assumption (LNT-assumption) as the basis of the protection system
- the system is claimed to be too sophisticated and therefore difficult to explain to lay people

It is also claimed that adding up small doses over large populations and geological time scales (collective doses) results in too high expenses in removing very low individual doses.

Professor Clarke makes a proposal, called ”Controllable Dose”, for revising the system. The essential change in the philosophy proposed is to move from the present dual system of individual and source related control to only control of the dose to individuals from sources that can reasonably be controlled, the principle being as follows:

> *”If the risk of harm to the health of the most exposed individual is trivial, then the total risk is trivial - irrespective of how many people are exposed”*

This change in philosophy would have several consequences according to the proposal:

- dropping the principle of justification
- need for reformulation of the principle of optimisation
  - replacement of ALARA with ALARP
  - abandoning the concept of collective dose
- not distinguishing between practices and intervention
- possibly no need to differentiate between occupational, public and medical exposure
- no need for the existing dose limit of 1 mSv/a for the public

While trying to find out in the Nordic Society for Radiation Protection whether a change in the ICRP approach was desired and whether Professor Clarke's proposal would be the path to go, a panel and a plenary discussion was arranged at the 12th ordinary meeting of the Society (2), complemented by a request for written comments from the members (inclusive members from the Baltic countries).

The emphases of the answers and comments, summarised below, varied depending on the experience and the field of work of the person in radiological protection (occupational, public, medical, natural exposure). No consensus of the views was sought among the members of the Society and the comments should not be viewed as the Society's position. They are merely issues that deserve a thorough discussion before deciding on major changes to the present ICRP System of Protection.

LINEAR-NON-THRESHOLD-ASSUMPTION

The LNT-assumption has never been challenged regarding the hereditary effects. Although this may not be correct for cancer induction it is still the most likely assumption, thus resulting in the most likely consequence assessment, though with large uncertainties, which should be pointed out.

As a consequence of the LNT-assumption the collective dose is a measure of the expected detriment. Some arguments against use of the LNT-assumption do not stem from different views about the biology, but from the misuse or misunderstanding of the application of the concept of collective dose.

The LNT-assumption is of great practical value as each exposure can be judged on its own account for doses in the stochastic area, without knowing the previous or future doses, which would be needed in practical radiation protection if thresholds were supposed to exist. It should be emphasized, however, that this is not an argument in itself for preserving the LNT-assumption.

CHANGE FROM THE DUAL SYSTEM OF INDIVIDUAL AND SOURCE RELATED APPROACH TO SOLELY INDIVIDUAL RELATED APPROACH - ABANDONING OF THE COLLECTIVE DOSE CONCEPT

The basic idea stated in the proposal that, if the risk of harm to the health of the most exposed individual is trivial then the total risk is trivial, is true as the total (the society) is the sum of the individuals, but is this all that we want to aim at? The essential question is whether the situation is acceptable if the expected harm can be further reduced by protection at a reasonable cost. It is a general view that it is unethical to leave further protection unimplemented if this can be done at a reasonable cost.

The solely individual-related approach would bring radiation protection back several decades, back to the ”chimney policy” of the fifties; *i.e.* the higher the chimney, the lower the individual exposure, without reducing the total detriment. This would be in contradiction to today's policy of environmental and public protection. Another example of its consequences is that in the case of food contamination, dilution would solve the individual risk problem without any reduction of the expected total detriment.

Thus, it seems essential that the limitation of individual risk also in the future should be complemented by a source-related judgement of total harm, based upon the collective dose and the linear-non-threshold-hypothesis of radiation risk, for which the owner of the source bears full responsibility. To give up this principle would not be compatible with ethics prevailing today.

As a consequence of the LNT-assumption collective dose is a measure of the expected detriment and is used to assess the total expected detriment from a practice or source.

However, this is not the only use of collective dose. This has been explained in ref (3). In optimising the protection, collective dose can in some cases, as in preventing global contamination from continued practices and multiple sources, be used as a mathematical tool regardless of the LNT-assumption. However, it is important to distinguish the doses in space and in time. In the above example of releases from a high stack it is tempting to trade higher doses to the own population for lower doses to larger populations in neighbouring countries (doses in space). If individual doses alone would determine the need for protection, high stacks are the obvious solution. But if optimisation of protection on the basis of collective doses were required, the solution would be more sustainable in the long run, i.e. less global contamination. Regarding doses in time a similar trading cannot be done and demand for optimisation for the same reason as above would be less obvious. Also in occupational radiological protection the sole reduction of individual doses can result in unjustified increase of collective doses unless both the individual- and source-related approaches are considered simultaneously. In the working culture, the ”ALARA”-thinking has shown very positive results, measured by trends of collective doses, wherever ALARA has been introduced.

Obviously the use of collective dose needs to be explained by ICRP much more thoroughly in its various applications in different sectors of radiation protection. Particularly important is clear guidance on issues that can lead to meaningless applications such as time-integration over infinitely long time periods, which ICRP already advises not to do. Still, all our commentators with one exception express as their clear view that the collective dose concept is important and useful in radiation protection and that it must not be abandoned.

JUSTIFICATION OF A PRACTICE OR INTERVENTION

The present ICRP recommendations specify that, when practices involving exposure or potential exposure to radiation are being considered, the radiation detriment should explicitly be included in the process of choice. The detriment being considered is not confined to that associated with radiation alone. It includes other detriments and the costs of the practice. It is true that the radiation detriment may be only a small part of the total. The justification of a practice, such as nuclear power plants, thus goes far beyond the scope of radiological protection. However, it should not be forgotten that also in such cases radiological safety of the practice is almost a prerequisite before the overall consideration of justification.

In the medical field the justification principle is essential. If a new practice is considered, *e.g.* screening for a given type of cancer, it is obvious that only if the expected number of cancer cases saved would exceed the expected number of cancers induced by the screening itself plus other costs of the screening practice, such a practice would be justified. Another example is the decision to introduce clean up of contaminated land. Again, only if the net benefit of clean up were positive, *i.e.* if the avertable doses and reduction in other negative attributes would exceed the costs, in simple words if more good than harm is the result, clean up would be justified.

In the received comments it was also emphasised that international recommendations should take due account of the problems in less developed countries. New practices, which add very small contributions to individual doses, may be unjustified for other reasons, and tools are needed to prevent such development.

The principle of justification would still be needed, both for ” practice- and intervention”- like situations. Justification is also a general ethical principle, and should, indeed, rather be introduced *e.g.* to other hazardous industries than abandoned from radiological protection. The fact that justification decisions are in some cases made by other bodies than radiological protection authorities is not a reason for abandoning it.

OPTIMISATION

In the existing System of Protection optimisation is the process of deciding on the level of protection to obtain a maximum net benefit, in other words do the most good. In simple terms, the difference between the benefits and the disadvantages, expressed in the same terms, should be positive (justified) and should be maximised (optimised) by setting the details of the radiation protection. The process of optimisation includes the collective dose - both for practices and intervention.

In the case of practices, the optimisation is by necessity a source-related process, and it will be subject to constraints. The ICRP introduced the use of constraints to provide a mean to deal with individual equity issues associated with the distribution of detriment from radiation exposure. Thus, source-related dose constraints are applied in the process of optimisation to limit inequity. In the case of intervention the use of such constraints is not required, as the aim is to improve an existing situation, *i.e.* to put people in a better position.

Contrary to the claim that optimisation, with very low doses included in the collective dose, requires too much funds to remove very low doses, it actually is the process showing when to stop spending more resources on protection. By definition, it does not go beyond the point where the detriment can be reduced with ”reasonable cost”.

For the purpose of optimisation of environmental radiation protection it is neither possible nor necessary to calculate collective doses over millions of years. However, the inclusion of small doses to distant populations precludes a build up of global contamination and is thus necessary for optimal protection, as mentioned earlier.

In occupational radiological protection collective doses were considered to have a very important role, when making choices between different protection options.

If the concept of collective dose were abandoned in a revised System of Protection the process of optimisation would need to be revised as all attention is shifted to individual doses. The principles of justification/optimisation always go together and these principles would then have to be redefined to cope only with individual doses. The change of ALARA to ALARP (as low as reasonably practicable) and the consequences for the optimisation process need to be elaborated. The role of source-related constraints would need to be revisited in the light of the proposed concept of investigation levels.

PRACTICES AND INTERVENTION

Although the formulations of the optimisation principle differ for practices and interventions, the practical implementation of optimisation is essentially the same process, whether it is considered in the context of the continuing operation of a practice, as part of decommissioning a practice, or for intervention. In all cases, it includes an evaluation of the different options available, how exposures can be reduced, and the choice of the option that results in the greatest benefit, considering all relevant factors that influence costs and benefits.

Some situations, *e.g.* clean-up situations, will clearly fall into one or the other of the categories - practice or intervention - but for others it will not be so obvious. In other cases, although the distinction and choice is clear, it may not be acceptable for the society to reach different conclusions for the level of protection, depending on the origin of the source of exposure. The suggested removal of the concepts of practices and intervention would probably create more problems than it solves. It might be better to formulate a general framework (justification, optimisation, individual protection, limiting inequities) that would include the principles of practices and intervention, but place them in a wider context in which they continue to provide guidance for situations that fit well into one category or the other. Experience has brought up a number of typical examples of ”boarder line cases”, *e.g.* where intervention situation is fading out and a new practice is created. Such interfaces could

be better characterised. For situations that do not fit well into either category, the framework should provide useful guidance that is independent of such a categorisation.

DOSE LIMITS - ACTION LEVELS

The Dose Limit of 1 mSv/a for the public is indeed an individual related limit given in the present ICRP recommendations as guidance for the authorities to watch the sum of the dose contributions from different sources, excluding medical and natural radiation. It cannot be directly measured and was not supposed to be continuously controlled and satisfied like the occupational dose limits. With justification and optimisation under source-related constraints, dose limits for the public have become of secondary importance and could therefore be abandoned. However, people need some reference values, with which they can compare their situation.

The proposed concept of controllable dose includes a maximum individual dose level, an Action Level, around some tens of millisieverts in a year. If controllable doses are above this level, action should be taken to reduce the individual doses. The management of controllable doses below the Action Level would be by individual-related source specific Investigation Levels. They would apply to different actions taken to reduce exposures at the source, in the environment or by moving people. They would cover, for example, occupational exposures, medical doses, doses from radon or from other elevated levels of natural radionuclides, and those after an accident. The action level/ investigation levels would replace the existing dose limits for practices and intervention levels/ action levels for intervention situations.

The practical application of investigation levels with regard to dose addition in ”practice”-like situations and dose reduction in ”intervention”-like situations needs to be clarified. If investigation levels are to be applied both as ”dose limits” and ”intervention/action levels”, the derivation of their numerical values needs further clarification. For instance should they be based upon justification/optimisation (constrained/unconstrained) of protection of individuals or populations (individual- or source-related protection), levels of acceptable risk to individuals or just upon generic values of reference levels that have been inherited from the existing System of Protection?

The set of inherited numbers in Fig.1 (1) explains the conversion of the present system into the system of ”Controllable Dose”. A number of questions rise, *e.g.* is this seen as relaxing the radiological protection (maximum level of controllable dose 20-30 mSv) or are people ready to accept any sources which give no more than a trivial risk (30 µSv) to the individual? Using such words as Action level or Investigation level or Constraint would not necessarily change the connotation of Limit to a lay person as much as for an expert. The numerical values may still mean the boundary between safe and unsafe for a lay person, but would the lowest value and not the highest be picked as the reference value? The possible psychological effects of the changes should be carefully considered, particularly as the aim of changing the System is to make it less complex.

Including medical exposures into the general framework of controllable dose seems artificial. The clinical judgement of what is necessary and optimal for the patient should not be influenced by any ”action level” defined for other purposes. The distinction between medical, public and occupational exposure should be kept.

Concerns were expressed regarding the possibility of decreased interest in the research on cancer induction by low doses, if the concept of controllable dose with the presented numerical values is adopted.

PROTECTION OF THE ENVIRONMENT

It is stated in the proposal of ”Controllable Dose” that it is probably no longer sufficient for ICRP to limit its recommendations to the protection of man. It is also believed that the proposed system would facilitate the development of an environmental protection strategy for radiation protection that is more compatible with those for other environmental agents.

The intention to develop such a strategy is welcomed and necessary. However, it is hard to see how the proposed system would facilitate such development if moving back to dilution approach, in other words stopping to prevent global pollution, abandoning the strict requirement that the ”polluter pays” his share of the environmental contamination and abandoning the precautionary principle built into the optimisation process applying collective doses. In other areas concerned about environmental contamination the trend is in the opposite direction.

The environmental protection aspects could be added to the present system in the same manner as any new aspects have been added to the Protection System throughout the years. This area needs a source-related approach. The present recommendations can be complemented by guidance on how to protect other species. Once the environmental protection strategy becomes clear, practical coherent guidance concerning both environment (other species) and man can be formulated in a manner which facilitates the control of facilities releasing different types of environmental contaminants simultaneously.

GENERAL COMMENTS

There seems to be a general agreement that the present System of Protection is complicated and difficult to explain even to professionals within radiation protection; there is a need for simplification and improvements of the System of Protection. However, even those who consider the present System too complicated warn against revolutionary changes without sufficient discussions of the consequences, because the changes can indeed cause more problems than they solve.

It was pointed out that such discussions should not delay the implementation of the present recommendations, which in many countries are only in the process of being introduced into the national legislation. Experience needs to be gained from the present system in order to see what needs to be changed. A completely new system would necessarily be an untested system.

There were serious reservations with regard to the implementation of a completely new System of Protection within a time period of only a few years. The existing system was developed gradually over a time period of seventy years. The road towards a new system seems rather long - a time perspective of twenty years was mentioned as realistic, also because the existing international directives and standards as well as national legislation have just adopted the ICRP recommendations from 1990.

Concerns were also expressed about the terminology, which has to be precise and translatable without changing the meaning.

CONCLUSIONS

It is seen as positive to have a wide, open discussion on the needs for improvement and simplification of the international radiological protection recommendations. However, no new scientific information is available that would call for a major revision of the present recommendations in the very near future.

The basic needs for protection have not changed, but the emphasis has moved to patient protection, long-time periods in nuclear waste disposal and environmental issues in

general, the last needing rethinking. A number of borderline situations, not fitting well in any category of the present system, have surfaced during recent years.

A possible solution could be to clarify those issues that cause most misunderstandings and problems, to complement the recommendations with guidance on protection of the environment, and above all to facilitate the application of the principles by giving practical guidance, even if this means less flexibility.

REFERENCES

1. R. Clarke, *Control of low-level radiation exposure: time for a change*?, J.Radiol.Prot.19(2), 107-115 (1999).

2. P. Hedemann Jensen, rapporteur, *Panel and plenary discussion of Controllable doses of low-level radiation - New ideas from ICRP*, Proceedings: Nordic Society for Radiation Protection, 12th ordinary meeting, Skagen, Denmark (1999).

3. B. Lindell, *Concepts of Collective Dose in Radiological Protection*. OECD/Nuclear Energy Agency, Paris 1985.

4. Contribution of the Canadian Radiation Protection Society (Draft Version)

The Canadian Radiation Protection Association understands that the ICRP have asked IRPA to solicit comments from all its member societies on the proposals for a revised philosophy for controlling all uses radiation which have been circulated by Professor Roger Clarke. The following review does not constitute an agreed consensus view prepared by all our members, as with other IRPA member societies we have found widely varying opinions about these proposals within our organization. Nevertheless the following is an attempt to report most of the viewpoints which our members have expressed, and to indicate where possible how widely particular viewpoints appear to be supported by our members.

(1) The need for changes in the existing approach to radiation control is widely accepted by our membership. With the present approach particular concerns arise from the concept of collective dose which follows logically from the linear-no-threshold theory, but several others are now also evident. The original use of the collective dose concept was to prevent an employer from claiming that he had improved radiation safety by dividing the same dose between different employees. The overall risk of a malignancy developing in a workforce of ten workers each receiving a dose of 10 mSv is, probably correctly, believed to be the same as that if the workforce was 100 but the average dose received was only 1 mSv. However many of our members question whether the same is true for a dose of 1 uSv to a population of 100,000. The LNT theory was introduced to provide a safe but conservative way of estimating total radiation risks, and those who introduced it were careful to emphasise that only limiting risk estimates could be derived in this way. Collective dose analyses involving individual doses below those for which epidemiology can demonstrate harmful effects, are therefore inherently flawed. A more serious misuse of this principle arises when collective dose calculations are made over extremely long time spans in order to predict the health consequences of radioactive materials in the environment. By calculating the sum of microscopic exposures to all members of an exponentially increasing population over many centuries, very large but potentially spurious health detriments are often derived. In Canada problems frequently arise with mining residues containing uranium or thorium where the almost infinite half lives, coupled with the additional complication of highly mobile radon releases, allow virtually limitless detriments to be calculated in a pseudo scientific matter. Such calculations are easily exploited by those groups aiming at terminating all uses of radiation, however beneficial.

Other problems have arisen where applying the ALARA principle consistently to different activities leads to very inconsistent treatment of comparable doses, and when attempting to improve the public perception of radiation risks. All workers recognise any radiation exposure, however small, as having an associated risk and trade unions are active to ensure that the ALARA concept is rigorously enforced under almost all jurisdictions. In Canada the result of this can be seen by reference to recent copies of the annual publication from Health Canada entitled "Occupational Radiation Exposures in Canada" which show that today very few radiation workers ever receive doses exceeding the maximum permissible level, and that this proportion is steadily declining as the ALARA concept bites deeper year by year. Whereas thirty years ago it was approximately one in every 1000 radiation workers, it is now about one in every 10,000. Nevertheless for all the job sectors considered separately in these publications, the average radiation dose does not now exceed the 1 mSv level permissible for unmonitored members of the general public and there are now no job

categories where it approaches even the former public dose limit of 5 mSv. This clearly demonstrates the value of implementing an ALARA policy, but unfortunately it can also lead to circumstances which impact adversely on public confidence in radiation control procedures. Consider two companies employing radiation workers where, even after all reasonable protection procedures have been introduced, the potential radiation hazards in company B are the greater. Despite identical dose limits, the implementation of ALARA may lead regulators to require company A to spend significantly more on reducing radiation exposures which, with little effort, are already well below those characteristic of company B. This will frequently create a situation where the workers in Company B quite unnecessarily feel they are being exposed to a serious level of hazard.

Similar concerns can arise over natural background doses, when employers who may have several different factories are being asked to introduce expensive new equipment for the purpose of reducing doses by an amount less than the differences in the background doses received by workers in their different plants. In the case of radon progeny, these doses may be as much as several mSv, although employees who are not be listed as radiation workers have an occupational dose limit of 1 mSv. Such inconsistencies make it difficult for current control procedures to retain public credibility. Other inconsistencies arises in the event of a serious nuclear emergency, where the normal ICRP recommended dose limit of 1 mSv/y for a member of the public is not to be implemented and alleviative actions are only expected when individual received doses are likely to be above 5 mSv, as well as with many diagnostic medical procedures delivering dose equivalents of several mSv.

Such problems would not be important if there was general recognition that, although epidemiology cannot demonstrate the dose response curve is linear and passes through the origin, there is reasonable evidence for believing this is the case. In practice however many CRPA members believe such evidence has been undermined both by recent developments in radiobiology and by a variety of epidemiological studies carried out among large groups exposed to low levels of radiation. More detailed comments on members views about the status of the LNT theory are given later.

(2) It is generally felt by most members of the Association that that the proposals put forward by Dr Clarke would lead to simpler, more coherent and more logically satisfying control procedures than those currently in place.

(3) Dr Clarke suggests that his new proposals would eliminate the need to differentiate between interventions and practices, this seems to be generally welcomed as logical. He also suggests that they might eliminate any further need for the principles of justification and optimisation. Many of our members feel that these principles have contributed an ethical basis to current radiation protection practices which will still be required; and which should, as a minimum, be brought in as part of a statement of the ethical basis on which ICRP recommendations are prepared. Finally Dr Clarke suggests that the new proposals will eliminate the need for collective dose assessments, or for continued discussion of the validity of the LNT theory. These suggestions are much more controversial, and are closely linked to the discussion on the public acceptability of the proposed changes which appears below.

(4) Ignoring trivial details such as the exact dose levels which will be identified as the various "action levels", CRPA members concerns about Dr Clarke's proposals fall primarily into the following categories:

(a) Some of our members believe that the ICRP are making too many changes in recommendations, and that this does not promote public confidence either in professional radiation safety specialists, or in the justification for the currently recommended dose limits. Some members take a slightly more extreme view, and believe that the current ICRP practice of continually updating recommendations helps anti-nuclear groups to promote the view that ongoing studies have continually shown radiation exposures to be more hazardous than previously thought, and have led to continued "ratchetting down" of earlier dose limit recommendations. These members believe that the most important requirement today is for a period of complete stability during which the profession can try to broaden the acceptability of the limits currently being enforced. This view is clearly incompatible with the changes being proposed by Dr Clarke.

(b) Other members do not believe that at the present time the radiation safety profession is ready to adopt the changes recommended by Dr Clarke.

(c) There is a more widely held feeling among other CRPA members that changes cannot at this time be successfully introduced by scientists alone on an ad hoc basis, and that any changes in the basis of our radiation protection practices will only be possible after the scientific reasons for the proposed changes have not only been explained to the satisfaction of the public but have also been generally accepted. In particular these members feel that the LNT theory appears very logical to most non-scientists and is therefore very widely accepted. Many of the current radiation control practices to which Dr Clarke is recommending changes (and in particular the collective dose principle) follow directly from this theory. Changes in these practices will never be generally acceptable whilst a significant part of the radiation protection community still regards this theory as essentially valid.

The four points above constitute a general review of what we believe to be the opinions of CRPA members on Dr Clarke's proposals. The appendix to this review attempts to assess the degree of consensus which appears to exist among our members about some of the specific issues identified by Dr Clarke in his paper.

APPENDIX

(i) Justification, Optimisation and Limitation.

Most CRPA members feel that these provide the only ethical basis from which appropriate radiation control procedures can be derived. However they would be more appropriate for an introductory discussion relating to how ICRP develops all its recommendations than as a formal part of specific recommendations applying to each control procedure that may be discussed.

(ii) Collective Dose.

Most members believe that ongoing analyses of collective doses, particularly in situations where any relevant numerical assessments are almost impracticable, does not contribute usefully to the development of control procedures optimised to provide the overall benefit to society. Nevertheless many are conscious of the fact that the use of this concept is fully legitimised by the LNT theory, and that it should remain with us whilst we continue to base all protection practices on this theory.

(iii) The LNT theory

As with most IRPA affiliate societies, the CRPA contains members firmly committed to the view that this theory should remain as the cornerstone of all radiation safety practices, as well as those who regard it as no more than an over-conservative working tool which has led to many of the problems that are faced by the profession today. To try and expand on this important issue a little, we must recognise that much of the confusion within the profession arises because some members think the LNT theory applies to the relationship between cellular damage and absorbed dose, whilst others believe it applies to the relationship between the incidence of a specific disease and absorbed dose. We believe a majority of our members now recognise there is no longer any radiobiological justification for the LNT theory in the second form stated above; and that the relationship between the received dose and either the likelihood or the time of incidence of any specific malignancy can depend upon many factors other than total dose (age, dose rate, fractionation, individual sensitivity etc.) It is generally recognised that there are probably also synergistic effects which will be specific to the individual. Many of our members would accept that such factors can lead at least to an effective threshold in the incidence of disease following low levels of irradiation; and that this effect must be considered whenever a collective dose assessment is made. A significant proportion of members go further and believe specifically in the existence of hormetic responses to disease incidence at low levels of exposure, but other firmly adhere to the traditional view that these have never been adequately demonstrated. In general it is probably true that most of our members do not believe radiation control procedures necessarily need to be based on theoretical relationships, whether these relate to an LNT or a hormetic response. This pragmatic approach tends to still put epidemiology above radiobiology when designing radiation regulations.

(iv) Dose Limits and Action Levels.

Although this would not be accepted by all our members, there is a lot of support for Dr Clarke's recommendation that there should only be one dose limit, somewhere in the 20-30 mSv/y range, and that other categories of exposure should be controlled through the use of

action levels. Our experience in Canada has generally been that action levels generally permit very effective control of radiation exposures.

(v) The need for changes in the present ICRP recommendations & ICRP based control practices.

Most CRPA members instinctively recognise that changes imposed from above are seldom effective, and that constantly changing regulations are very counterproductive to the development of public confidences in radiation control professionals. This public confidence is felt to be the most critical concern facing the profession, and many our members believe that we need to increase public understanding of the basis from which present protection practices have evolved, and of its theoretical and practical limitations, before we attempt to make significant changes in these practices. Whilst a majority of CRPA members firmly believe that the time for changing to a simpler and more logically consistent basis for radiation control is overdue, many of them also believe this objective will not be readily achieved if we put the cart before the horse and ignore the issue of public acceptability.

CRPA MONTREAL CONFERENCE - CONTROLLABLE DOSE PROPOSALS

QUESTIONNAIRE FOR ALL CRPA MEMBERS

The ICRP are attempting to evaluate the views of all radiation safety professionals on the merits of the controllable dose proposals formulated by Professor Roger Clarke as an alternative basis for the development of radiation protection practices and regulations. To this end the International Radiation Protection Association has requested all its member societies to submit a brief review summarising the views of the radiation control experts in their own country. CRPA is of course one of the Associations which is being asked to forward comments in this way. Your Directors have therefore prepared the following draft statement based on the comments about these proposals which have been made by CRPA members in our Bulletin, on our website and in other ways. To enable this draft statement to be revised so that it more accurately reflects the views of our members before it is submitted to IRPA the Directors are seeking members comments both here at this meeting and through the Association website. Please take a few minutes to list any comments or concerns which you may have with any part of the draft statement attached below; and, even if you have no general comments to make, please answer the specific questions listed below. Your comments, together with your answers to this questionnaire, can be placed in the box provided at the Registration Desk.

(1) Do you agree with Professor Clarke that it is time for a change in the present ICRP approach to radiation control?

YES/NO

(2) Do you agree that the recommendations Professor Clarke has made would remove the need for consideration of justification and optimisation in the development of ICRP recommendations? YES/NO

(3) Do you believe that the collective dose principle should continue to be used?

YES/NO

(4) IF YOU ANSWERED YES TO QUESTION 3, do you believe that it is valid for use at all levels of dose and over any period of time? YES/NO

(5) Do you believe that the Linear-No-Threshold (LNT) theory has been established:

(a) for cellular damage resulting from ionizing radiations YES/NO

(b) for the incidence of radiation induced malignancies YES/NO

(6) Do you support the suggestion that there should only be an upper dose limit and that all other limits should be replaced by action levels? YES/NO

(7) Do you believe that such a revision of radiation protection practices would be acceptable to the public without an adequate prior public consultation procedure? YES/NO

Results of the questionnaire :

Question	1		Yes	100%
	2		Yes	33%
	3		Yes	33%
	4		Yes	0%
	5	(a)	Yes	20%
		(b)	Yes	6%
	6		Yes	94%
	7		Yes	27%

5. Contribution of the French Radiation Protection Society

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INTRODUCTION

Following the invitation from the International Radiation Protection Association (IRPA) to comment on the article written by Professor Roger Clarke entitled “Control of Low Level Radiation Exposure: Time for a Change?” [1], the Board of the French Society for Radiation Protection (SFRP) decided to set up a working group (WG) on “controllable dose”. The latter consists of some twenty members representing the stakeholders involved in radiological protection in France: authorities, experts and professionals from nuclear, medical and research fields as well as associative movement (see detailed list of members at the end).

Radiological protection standards are elaborated within cycles, beginning with the drawing up of a summary statement of scientific knowledge at international level and ending, several years later, with the updating of national regulations. In the meantime, several international organisations, governmental or not, take it in turn to recommend standards to States, making allowance for the feed-back experience from standards application and for the most recent scientific, technical, economic and social aspects. The International Commission on Radiological Protection (ICRP) plays a key role in this process since the regulations in force in the majority of States refer to its regularly published recommendations.

The last cycle, marked by the Publication 60 of ICRP [2], is coming to completion with, as far as the Members States of the European Union are concerned, the transposition of the Directive 96/29/Euratom [3] into national law. A new cycle is beginning. The final result, a few years from now, will be a new generation of ICRP recommendations. In this context, it is worth considering the way in which the previous radiological protection systems operate, without necessarily calling it into question completely.

It was in this context that the WG received R. Clarke’s article. It was interpreted as a preliminary proposal intended to widen the process by which standards are drawn up by encouraging dialogue at international level. Taking R. Clarke’s article and its own thoughts as a basis, the WG set itself the aim of formulating questions and proposals for submission to the ICRP. The WG made no attempt to make a complete break with the past but gave thought to the appropriateness of the radiological protection system as a whole and the improvements which could be brought to make it clearer and more operational. The WG’s processes was structured by four issues :

- basis of the radiological risk management system,
- exposure situations,
- risk management indicators and tools,
- implementation of these elements in the radiological risk management system.

After several months of work, the group is far from having exhausted the subject but it considers itself in a position to contribute, on behalf of the SFRP, to the international debate on how the radiological protection system could evolve. This article, which has been approved by the Board of SFRP, summarises the findings of the WG at the beginning of the year 2000.

1 - BASIS OF THE RADIOLOGICAL RISK MANAGEMENT SYSTEM

The radiological protection system is based on scientific knowledge of the biological effects of ionising radiation. The WG acknowledges that the effects of low-level radiation doses are fuelling persistent scientific controversy, particularly when it comes to deciding whether or not there is a threshold in the dose/effect relationship [4] [5]. Science is progressing and the way forward is becoming clearer but as yet, there is still no consensus. In the meantime, the large majority of the WG members agree that the hypothesis of a linear non-threshold dose/effect relationship, corresponding to a caution attitude, continues to be appropriate as far as radiological risk management is concerned. The assumption that a risk exists regardless of the dose implies that there must be a responsible risk management policy based on the three general radiological protection principles, i.e. justification, optimisation and limitation.

However, for the WG as a whole, the radiological protection system should make a clearer distinction between scientific and risk management aspects. In particular, it is important to specify that the linear non-threshold relationship is a hypothesis which could be under or over estimating for certain exposures and has the effect of assuming that a risk exists for dose ranges for which it has been neither proven nor disproven scientifically.

In his article, R. Clarke indicated that “in respect of current knowledge it has been argued here that the evidence weighs against the concept of a low dose threshold and favours the existing judgement that tumour risk will rise as a simple function of dose even at very low doses and dose rates. That is not to say that dose thresholds for tumour induction are not biologically feasible”. He adds that “radiological protection systems need to be as simple as possible and to focus on the general consistency of all relevant data, not just the inevitable biological intricacies and exceptions”.

In his opinion, “ICRP judges that the weight of evidence at present falls in favour of assuming that those radiation events are potentially disruptive from the lowest doses. And while apoptosis, cellular surveillance, immune and adaptive responses are all real, they are most likely to modify the shape of the dose-response curve rather than proving a threshold”. He deduces that “the major policy implication of a non-threshold relationship for stochastic effects is that some finite risk must be accepted at any level of protection. Zero risk is not an option and this leads to the three principles that comprise the current policy of the Commission: justification [...], optimisation [...], limitation [...]”.

Thus, the large majority of the WG members agrees with R. Clarke that it is appropriate to adopt the hypothesis of a linear non-threshold relationship and acknowledges the same implications for radiological risk management.

According to R. Clarke, this hypothesis has to be deemed in the light of legal aspects : “increasingly, science is judged in the courts rather than by national academies of science. Judge and jury are increasingly likely to decide the issue and it is they who must be convinced as to whether there is a threshold and thus no risks at low doses of radiation”.

The WG notes, that in France, the recourse to legal action is less frequent than in certain countries but could become increasingly common, particularly now that the concept of putting another person’s life in danger has been introduced into the penal code. In this respect, legal cases concern the protection of both workers and the public.

Furthermore, the WG noted that judges in France do not generally give a verdict on the existence of a risk but rather on the actions undertaken to manage it (particularly the implementation of the precautionary principle). Consequently, even in prospect of legal cases, it seems less relevant to determine a threshold below which the risk would be considered as trivial or non-existent than to demonstrate that mechanisms had been set in place to make the risk acceptable to those exposed to it. But the idea of an acceptable risk is

relative: the risk is not acceptable in itself but as a function of the exposure situation being considered.

2 - EXPOSURE SITUATIONS

There are a multitude of exposure situations. The existing system divides them into categories for management purposes: practice/intervention, occupational/medical/public, natural/artificial/enhanced-natural etc. Some of these divisions are relevant, other are ineffective. Would a different way of classifying exposure situations be more operational?

In his article, R. Clarke, noting that certain situations "do not easily fall into the current definitions of practice or intervention" considers that "radiological protection philosophy might usefully be re-examined in order to develop an alternative logically consistent framework for protection to that used at present". He proposes to "bring the three categories of exposure, occupational, medical and public, within an overall framework that encompasses the present system of protection for practices and interventions."

The WG, for its part, has tried to identify and characterise the various exposure situations, including those which were experienced in the past and which are nowadays considered as unjustified. The three components of an exposure situation are the source, the context giving rise to the exposure and the individuals exposed. The WG began by listing all the exposure sources. They were divided into two major categories: sources of natural origin (cosmic or terrestrial gamma radiation, radon and other naturally-occurring radionuclides) and those of artificial origin (sealed and non-sealed sources, radiation generators etc.). For each source, it noted the various contexts giving rise to exposure (in the industrial or medical fields, inside buildings, caused by the use of consumer products, in radiological emergencies or due to lasting exposure etc.) and the categories of individuals exposed (occupants of houses, users, consumers, exposed or non-exposed workers, patients, future generations etc.).

Criteria characterising the situations in an appropriate manner as regards risk management were then established:

- according to how easy it is to directly measure the doses received by each exposed individual,
- according to the possibility of implementing an action to control the dose: this possibility is considered as being strong or slight but never zero (when it is not possible to take action on the source, it is always, in theory, possible to mitigate the exposure of individuals from this source, even if it is a natural one); on the other hand, it may not be relevant to take any action (for example, it is not considered appropriate to have people spend less time in mountainous regions even though they are more exposed to cosmic rays there),
- according to the benefit for the exposed individual of the exposure situation: the benefit may be direct (in the case of patients), indirect to varying degrees or non-existent,
- according to the finality of the radiological protection, distinguishing between:
  . situations in which radiation is used deliberately: the objective in this case is to increase exposure by as little as possible (making allowance for the optimisation principle); these situations can be likened to the "practices" referred to in ICRP Publication 60,
  . situations in which the radiation source is present *de facto* (for example radiological emergencies or lasting exposure): the objective in this case is to reduce exposure as much as possible (making allowance for the optimisation principle); these situations correspond to the "intervention" concept referred to in ICRP Publication 60.

Some of these criteria were also identified by R. Clarke who considers that "the significance of a level of controllable dose depends on its magnitude, the benefit to that individual and the ease of reducing or preventing the dose".

The analysis made by the WG revealed the large range of various and complex exposure situations. These situations are experienced by players from very different backgrounds and cultures and not all are governed by the same management authority. The characteristics and corresponding risk levels vary, considerably at times, from one exposure situation to another (for example the risk run by someone living in the vicinity of a nuclear facility is not the same as that run by a patient undergoing radiation therapy). Lastly, the WG notes that the risk acceptability remains closely connected with the specificity of exposure situations.

The WG concludes that simplification whereby exposures of all origins for a given individual are managed together in a global approach is not feasible.

3 - RISK MANAGEMENT INDICATORS AND TOOLS FOR THE IMPLEMENTATION OF THE GENERAL PRINCIPLES OF RADIOLOGICAL PROTECTION

The WG has not yet completed its analysis. Thought should be given as to how the various exposure situations can be grouped into families as a function of their characteristics. Then, suitable management methods should be determined for each family.

At present, the radiological protection system provides professionals with a series of indicators and tools for managing exposure situations (dose, dose limit, dose constraint, individual dose, collective dose, level of investigation, of action, of intervention, of exemption, of clearance, critical group etc.). They are used when implementing the three basic radiological protection principles defined by the ICRP (justification of practices, optimisation of protection and limitation of individual exposures). Which indicators and tools are really useful? For whom? To do what? How are they used? The WG considers that these questions have to be answered before the radiological protection system can be changed to make it more operational. As far as the group itself is concerned, it has focused on a few indicators in the framework of implementing the principles.

The principle of justification

Although the principle of justification is a regulatory requirement, its application is vague, not always subjected to a formal procedure nor sanctioned by a decision. Can a practice be taken as being justified just because it is subject to the regulatory control system? Who decides whether or not an exposure situation is justified (in reality, it is not always a government authority)? The way in which the principle is worded in ICRP Publication 60 can be interpreted as the need to put the advantages and detriments associated with the practice into a mathematical equation. But these elements are very difficult to quantify. Furthermore, the ICRP points out that, in most cases, the radiological detriment caused is just one of the disadvantages of the practice and that it carries little weight in the authorisation decision making process [2].

The WG also notes that the question of justification often arises in an optimisation context. Overlapping between the justification and optimisation principles seems more frequent downstream, i.e. closer to the exposure situation (justification of a given task at worksite level) than upstream (justification of a practice which may be nuclear power or the use of radiation for medical purposes). Thus, the justification of a practice seems to be less operational than that of an exposure situation. In the latter case, it is often not dissociated from optimisation, which is not always desirable.

According to R. Clarke, “since radiological protection essentially plays such a minor part in a government’s decision to justify the introduction, or the continuation, of a given use

of radiation, consideration should be given to dropping the principle of justification from the ICRP system". The members of the WG are not in favour of this solution. Even though it is rarely applied, judging by appearances at least, the principle remains usefully applicable in a number of cases. Moreover, it provides a generic framework for the implementation of the radiological protection system.

Thus, application of the justification principle to exposure of a patient is a key element of the risk management system in the medical field, particularly since dose limits do not apply. The ICRP has established three levels at which this principle should be applied in this field [6]:

- justification of the use of radiation in medicine,
- justification of a given medical procedure,
- justification of the use of a procedure for a given patient.

More globally speaking, this principle is evoked to motivate the banning of certain practices at a general level (the deliberate addition of radioactive substances to foodstuffs, toys, personal ornaments or cosmetics) or at a more particular level (feet radioscopy to determine shoe size, use of a radioactive source in the grain gauges of combine harvesters, etc.). Questions about the radiological impact of an exposure situation before its creation - or its remediation - is therefore to be profitable, even though it should be clearly pointed out that this approach does not necessarily lead to the banning of situations. If the question of justification does not arise specifically, the system could, in the most extreme cases, lead to optimisation of unjustified situations.

The justification of risk situations, the transparency around their management methods and, at times, more active involvement of stakeholders within the decision making process, are being increasingly requested by society as risk acceptance conditions. In case of dissatisfaction, legal action may be taken.

Thus, it is the opinion of the WG that the principle of justification has a part to play in a responsible radiological risk management system, whatever the context, since it is a way of appraising risks and accounting for how they are managed. Nonetheless, the WG recognises that application of the principle is hindered by the lack of procedures and objective criteria which would make it more operational.

The WG invites the ICRP to propose such criteria and to consider application of the principle in situations not currently covered by the radiological protection system (natural exposure or very slightly enhanced natural exposure).

The principle of optimisation

R. Clarke advocates a new definition of the optimisation principle. He suggests replacing "as low as reasonably achievable" (ALARA), which, in his opinion, has been associated with cost/benefit analysis and with the use of collective doses, by the expression "as low as reasonably practicable" (ALARP).

To the French way of thinking, it is difficult to understand the slight difference between ALARA and ALARP. The WG points out, however, that optimisation is not associated only with the elements quoted by R. Clarke but also involves numerous other criteria such as individual dose, technical feasibility etc. Furthermore, its implementation is integrated in a radiological protection culture, overstepping cost/benefit analysis.

R. Clarke is of the opinion that the protection of the individual is the main concern in risk management. For him, "if the individual is sufficiently protected from a single source, then that is a sufficient criterion for the control of the source". He sets up the principle that "if the risk of harm to the health of the most exposed individual is trivial, then the total risk is trivial - irrespective of how many people are exposed". Further on in his article, R. Clarke

expresses differently the same idea: “since the proposed policy of protection ensures that if the most exposed representative individual is sufficiently protected from a given source, then everyone else is also sufficiently protected from that source”.

This principle, with its different wordings, is not devoid of ambiguity. While there is no problem from a biological point of view, since individual sensitivity to ionising radiation is already taken into account in risk assessment, it can be contested from an epidemiological viewpoint. It does not work if the risk is not trivial, it is devoid of any real meaning in the medical field and it does not correspond to risk management philosophy in other areas. This principle should be filled out before an application can be found.

Another implication derived by R. Clarke from his new principle is that: “there would be no use made of collective dose as currently defined”. This prospect was not approved by the majority of the WG members. While welcoming the strengthening of individual protection, they are warning against a carelessness of the collective aspect of protection.

It is true that using a collective dose can lead to wrong perception of the risk to the collectivity, particularly when it is calculated by adding very low individual doses of a large number of individuals over long periods. Even the ICRP has warned against using the concept of collective dose in this way [7]. Nonetheless, it is relevant to make allowance for both individual and collective doses, even if the management tools are different. The collective dose concept should be retained as a management tool for protecting both workers and the public.

Moreover, with some precautions, the collective dose can be used as a risk indicator. In the opinion of the WG, it shall not be used to express an excess risk without providing the parameters delineating the context (population involved, time and space truncation). However, it is suitable for putting into perspective one risk with another or for assessing the effectiveness of radiological protection options.

R. Clarke also echoes the concerns of many people about the cost of decommissioning nuclear facilities or remediation of contaminated sites: “too much money is being, and will be, spent to achieve low levels of residual contamination”. In order to alleviate this concern, in the absence of a threshold in the dose/effect relationship, some suggest determining a “trivial dose” level, i.e. one below which the risk would be “so low as to be beneath regulatory concern” and thus “there would be no need to involve any system of protection”. R. Clarke suggests that the trivial dose level should be set at about 30 microsieverts. The corresponding risk is “commonly regarded as trivial”.

The members of the WG are divided on this question.

A few consider that it is legitimate to set at the international level an order of magnitude of risk regarded as trivial and the corresponding dose. This level would be a reference level based for example on enquiries on human behaviour and preferences. The determination of such a level should not exclude a debate on risk acceptability involving stakeholders where relevant, for example when confidence is weaken.

All the others are of the opinion that it does not exist a risk trivial in itself but only a level of risk accepted in a given context. It is therefore irrelevant to fix a pre-set dose level at which the risk would *a priori* be qualified as trivial. Certainly it exists, for the majority of exposure situations, a dose level below which it is no more appropriate to take any action to further reduce the risk. However, this level differs from one situation to another. It should be determined on a case-by-case basis by applying the optimisation principle, in the framework of a dialogue between stakeholders and under authority control.

Indeed, the optimisation principle means in essence that the effort to reduce doses should be stepped up with the characteristics of the exposure situation. In the complete wording of this principle, the term “reasonably” and the extension “economic and social factors being taken into account” indicates that it is not appropriate to systematically try to

achieve zero risk. At any given moment, it is therefore reasonable to stop trying to reduce the risk while keeping in mind that no concern does not mean no impact. This moment may be identified by a dose level which will not be generic but specific to the exposure situation. The identification of such a dose level should not lead however to slacken the vigilance because the implementation of optimisation principle should be seen as a continuous incentive to go forward.

Most members of the WG consider that building the system of radiological risk management depends admittedly on what experts have to say about trivial dose levels but mostly on concrete, constructive explanation of the factors taken into account for assessing exposure situations and the creation of protection policies. This approach would fuel the debate on residual risk, perhaps by encouraging greater involvement of stakeholder in the decision making process. The new recommendations to be published by the ICRP should emphasise the importance of optimisation to testify to the application of responsible risk management.

Another aspect of the optimisation principle which deserves to be examined by the ICRP is the need to appreciate the occupational risk as a whole. Workers are indeed subjected to a multitude of nuisances (heat, noise, enclosed spaces, moving in congested areas, noxious vapours, ionising radiation etc.) and exposure to radiation is just one aspect of their working conditions.

The principle of limitation of exposure

The individual dose limit is a dose level which, by law, shall not be exceeded (it is an offence to do so). It applies to the total dose received by an individual from all the sources taken into account in the radiological protection system (practices).

The WG is of the opinion that the dose limit is a relevant and indispensable reference for the protection of exposed workers, whose individual dose monitoring system allows to know the exposure resulting from their whole occupational activity. The relevance of a dose limit for the public is less obvious since it is impossible to measure the individual dose resulting from whole sources. R. Clarke emphasises the confusion arising from a misunderstanding of dose limits, particularly as far as the public dose limit is concerned. With the system he proposes, “there would be no need for the existing 1 mSv dose limit for the public”. It would disappear to make way for the principle of “control the dose to the representative member of the most highly exposed group”.

Insofar as the WG has fully grasped the concept of controllable dose, it means a dose, whatever the exposure situation, included in a range defined by two criteria: one quantitative (doses which are not unacceptable) and the other qualitative (doses which can be reduced or prevented, without significant disruption to lifestyle). In R. Clarke’s article, controllable doses are written out on a dosimetric scale. They are ranged between a maximum level unacceptable to exceed, unless human life is at stake (set at around 30 millisieverts) and a minimum level below which “there should be no need to consider protection of the individual” (around 30 microsieverts).

The reticence expressed by of most members of the WG as regards pre-setting a trivial dose level has already been mentioned. The same is true for the pre-setting of a single dose level for which the risk would be considered as unacceptable regardless of the family of exposure situations. For example, 30 millisieverts cannot be considered to be a high level where medical exposures are concerned. The problem is that, already mentioned, of the global management of exposures from various origins by referring to the same dose values.

In R. Clarke's article, the maximum acceptable dose is called "action level" and the levels below it are called "investigation levels". This terminology is unsatisfactory since it means that it is possible to wait until the maximum dose is reached before taking any action.

The WG recognises that as far as experts are concerned, the dose limit does not represent an operational referent for managing public exposure. However, most of the WG agree that it would be unrealistic to stop using it in the radiological protection system: an individual limit must be set which borders the range of doses in normal situation, applicable to all individuals, as is the case for the management of all risks due to toxic and carcinogenic substances.

Furthermore, most members of the WG are of the opinion that setting a source related dose limit is not a cure-all. Indeed, if it were to be determined by breaking down the multi-source limit, a necessarily arbitrary denominator would have to be used. In another hand, flexibility is useful for making allowance for the various characteristics of sources: the contribution of a source may appear to be greater than that of the others as soon as they have all been optimised and the total does not exceed the pre-set limit. A system with a limit making allowance for all sources is obviously more complex than one using a source related limit. It therefore has to be transparent and substantiated.

In this context, it seems indispensable to explain the method used to check compliance with the public dose limit. Exposures due to a source are evaluated for a member of the reference group (the group of more highly exposed individuals). The contribution of other sources would have to be added to this. The reference group method can cope with this but several questions arise. Should this group be hypothetical and as penalising as possible or should it be realistic? For a given source, should there be one single reference group or one per exposure pathway (external exposure, ingestion, inhalation)? Where should the reference group be placed to take account of the other sources: close to the source in question or at the intersection between the various sources located in the same area? Should another method be adopted, consisting of tracing isodose curves around each source then detecting any "hot spots" at the intersections? The ICRP could provide advice on these questions.

Moreover, there is a single source related indicator which use is to be recommended for the protection of both workers and the public. This is the individual dose constraint, the level of which is set and applied on a case-by-case basis to facilitate optimisation. The dose constraint makes it possible to integrate feedback experience and know-how at any given moment for any given practice, independently of the dose limit. The collective dose may also be subjected to a constraint.

As far as the public is concerned, the dose associated with the release limits is sometimes likened to a dose constraint. Nonetheless, it is important to make a clear distinction between the two concepts since release limits have regulatory status and it is an offence to exceed them, but this does not apply to dose constraints. Some WG members would prefer to use a dose constraint for the management of the public exposure rather than a source related dose limit, since the former is not legally binding. At the opposite, some others are in favour of a source related limit to be used as a binding indicator.

As far as workers are concerned, individual dose constraint has several objectives, depending on the case: making allowance for each exposure source integrated into the calculation of the total dose (for example miners who accumulate exposure to radon, dust and gamma radiation); organising the distribution of individual doses at worksite level in the framework of a collective dose constraint (exposure smoothing); facilitating the management of exposure of temporary or itinerant workers.

In all cases, it is essential that the value of dose constraint be set on a case-by-case basis rather than once and for all in ICRP recommendations or national regulations.

4 - CONCLUSIONS FOR THE EVOLUTION OF THE RADIOLOGICAL RISK MANAGEMENT SYSTEM

The main difficulty encountered when implementing the existing system, as highlighted by R. Clarke, resides in application of the ICRP risk factors to low doses. No matter how real this problem is, it should not be the claimed reason nor the only concern for establishing a new radiological protection system. The first step should be to note all the situations for which the existing system works well or less well (poor understanding of system, unsuitable tools etc.). Generally speaking, it works well for the protection of workers but less well when the public and radiological emergency situations are involved and badly for lasting exposure situations (contaminated sites, enhanced natural exposure).

Most of the WG are of the opinion that there is no need to completely rework the system in order to sort out these difficulties. It would nonetheless be useful if it evolved to become more operational and more understandable to those in charge of its application and those confronted with it (judges, the public etc.). Others are in favour of drastically simplifying the system and completely reworking the concepts it involves. All agree that the next recommendations to be published by the ICRP should be turned onto a more realistic way (which would not exclude a penalising approach), in other words they should be tested beforehand in practical situations to see whether or not they are operational.

Several proposals have already been put forward. They are intended to provide the ICRP with lines of thought, notably:

- not to turn the system onto the management in a global way of the exposures of all origins for a given individual,
- to make a clear distinction between the different categories of exposure situations and to identify for each one the corresponding management methods as well as the relevant tools and indicators;
- to keep the general principles (justification, optimisation and limitation) in the future system and to build concrete methods for their implementation,
- to underline the importance of justification and optimisation as attesting to the application of a responsible management of risk; the implementation of these principles leads to concretely and constructively explain the factors taken into account when assessing exposure situations and drawing up protection policy,
- to explain the method used to verify compliance with the public dose limit; in particular, to consider the way in which reference groups are used,
- to think about the ways of grasping the occupational risk as a whole, making allowance for nuisances other than ionising radiation.

These lines of thought lead to prospects for evolution, some of which have been taken on board by the WG.

Improve dialogue between stakeholders

Further dialogue between stakeholders on the issue of radiological risk management would help to explain what is at stake, the criteria affecting decisions and the factors to be taken into account. In the case of contaminated sites, for example, one approach is becoming apparent: decentralised risk management. Dialogue between stakeholders is indeed a crucial part of the decision process as regards risk activities. It allows to win or recover confidence where relevant. The establishment of procedures allowing for more active stakeholders involvement in decision-making process could also be useful in certain cases, particularly for

determining the acceptable risk level for corresponding exposure situations. The new recommendations to be published by the ICRP should take all these elements into account.

Provide means for an individual appraisal of risk

The “subjects to the risk” should have access to information on the various exposure sources they encounter with estimates of the corresponding individual doses and associated risks, put into perspective as regards other risks, if necessary. This would help to facilitate the individual understanding of radiological risk, to improve the transparency around the management of this risk, to encourage dialogue between stakeholders, and thus to develop a radiological protection culture. On this basis, each individual could total the doses he/she receives and come to his/her own conclusions about the radiological risk to which he/she is exposed. Doses would be grouped together for assessing individual risk but the corresponding exposure situations would continue to be managed according to their specificities. The ICRP could recommend that information of this type be made available.

Protect the environment

As quite rightly emphasised by R. Clarke, the issue of protection of the environment should be raised and the ICRP should take this into account in the forthcoming set of general recommendations. More detailed thought will have to be given to this since there are as yet no radiological risk management criteria for the environment. Two aspects will should be dealt with:

- protection of the environment with a view to protecting man in the long term (making particular allowance for bio-accumulation phenomena): this has already been taken into account in recommendations published by the ICRP but guidelines as to how to implement it practically would undoubtedly be useful,
- protection of the environment as such (fauna and flora). The objectives of which should be, in one hand, to ensure the preservation of the bio-diversity, i.e. the protection of the many varied species and not of the individual members of them and, in an other hand, to ensure the cleanliness of our natural heritage which has to be preserved for symbolic, cultural as well as economic reasons.

ACKNOWLEDGEMENT AND PERSPECTIVES

The French Society for Radiation Protection thanks very much Roger Clarke and more generally the ICRP for letting her share of the dialogue at international level through the agency of IRPA. She is standing ready to contribute actively to the preparation of the next generation of radiological protection standards, whenever the ICRP deems fit.

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6. Contribution of the Australian Radiation Protection Society

David Woods, President, ARPS

On the 20 November 1999, Prof Klaus Duftschmid, IRPA President, called upon the Presidents of IRPA Associate Societies to canvass opinion and comment from the members of each Associate Society on the concept of Controllable Dose as put forward in Prof Roger Clarke's paper " Controllable Dose: A discussion on the control of individual doses from single sources," August 1998.

Prof Clarke has since refined this paper and published it in the Journal of Radiation Protection Vol 19 No 2 pp107-115 in June 1999 under the title " Control of low-level radiation exposure: time for a change? " Both papers were circulated to the ARPS membership for comment, which culminated in a Workshop on Controllable Dose held at the ARPS 24th Annual Conference in Margaret River, Western Australia, 24 August 1999. The views presented here encapsulate the diverse opinion provided by ARPS members ranging from support for to opposition to the proposals.

At the heart of the matter is the acceptability or otherwise of the continued use of Linear No Threshold (LNT) hypothesis. ARPS has its advocates on both sides of this argument. Delegates to ARPS 24 were fortunate to listen to a keynote address by Prof Otto Raabe, past President HPS, on evidence supporting nonlinear effective threshold dose-response relationships for radiation carcinogenesis. The evidence presented was strong and indicated that for some radiations and end-points the dose response relationships are non-linear and have thresholds.

Notwithstanding this and other evidence referred to in Prof. Clarke’s paper, the use of the LNT hypothesis is a useful tool in radiation protection practice and allows risk and dose to be compared in the occupational exposure dose range and high radiation exposure dose range. At low doses and particularly at doses below regulatory concern or when applied to low individual doses applied to large populations, its use is questionable and indeed can lead to misinterpretation and misapplication with respect to environmental controls and safeguards.

Although it appears that Prof Clarke has come up with the Controllable Dose proposal as a direct consequence of the LNT hypothesis debate, his proposed table of Controllable Doses utilises the LNT dose response relationship. Without this relationship the foundation of radiation protection practice and principles as we currently know it is in jeopardy in the absence of a suitable alternate. An alternate to the LNT hypothesis has not been presented.

It is clear that the LNT hypothesis cannot be proved at low doses, however, its continued use is supported as a radiation protection tool, in that it has enabled the practical implementation of successful radiation safety controls and practices for four decades. It errs on the side of safety in that it is more likely than not to overestimate the risk from a given dose. A clear statement of its inapplicability at low doses is appropriate, to prevent its misuse. It is noted that for a quarter of a century the ICRP has been indicating that the uncertainty of the hypothesis at low doses should be taken into account in decision making to guard against inappropriate courses of action, for example see ICRP 26 para 30.

The current ICRP philosophy is based on acceptable risk and relates risk to dose via the LNT hypothesis for the purposes of practical implementation of radiation protection principles and in the setting of individual dose limits. Prof. Clarke's definition of Controllable Dose refers to doses "that can reasonably be controlled." Implicit in this definition is the word "reasonable", which relates directly to what is acceptable. What is reasonable to one person may not be reasonable to another. Therefore, "what is reasonable" needs to be clearly defined.

In considering the issue "what risk is acceptable" socially, politically and economically, a holistic approach should be taken to risk. Radiation risk is just one component of the total risk that a person is subject to, and judgements need to be made on the whole picture and not just one piece of it.

With respect to radiation risk, clearly, a two pronged approach is required, control of dose and control of risk. ICRP's current philosophy embraces both of these with respect to interventions, control of sources and practices, and its system of dose control (Justification, Optimisation and Dose Limitation). Prof. Clarke's paper argues for a dose control approach. A number of ARPS members argue that it is the level of risk that should be controlled. Clearly we need to control both the doses and the risks. We also need to convey the significance of a particular dose with respect to the level of risk it represents and answer the question "Is it safe?"

To practicing radiation protection specialists the ICRP recommendations have been held in high regard as scientifically based with the level of sophistication increasing with each iteration. The concepts of justification, optimisation and dose limitation are logical and well understood and easily communicated to a lay audience. The concept of effective dose is a powerful dose control tool. The Controllable Dose proposal is presented as a political compromise rather than being presented with scientific argument. It is attractive in its simplicity but is also potentially subject to misapplication and misinterpretation.

In his introduction, Prof Clarke refers to concerns about the application of risk factors at low doses. His proposal in this paper does not remove those concerns as the controllable dose table directly compares risk and dose in a linear relationship.

In the section on epidemiological evidence Prof Clarke concludes that the problems of estimating risk at occupational and environmental exposure levels remain. His paper does not provide an alternative method for risk estimations. There remains a need to analyse population exposures for prospective planning.

In the section on mechanisms of carcinogenesis Prof Clarke essentially concludes that the weight of evidence falls in favour of lowest doses being potentially disruptive with some corresponding finite non zero risk and restates the ICRP Principles:
Justification: Do more good than harm.
Optimisation: Maximise the margin of good over harm.
Limitation: Individual risk should not be unacceptable.
This argument supports a no change approach.

In defining the problem Prof Clarke highlights the key issue as the clean up criteria for contaminated land and its associated historic liability. In particular the misuse of collective dose in which very small doses are summed over large populations and long timescales to commit resources today to protect the future. Therefore the issue is primarily in relation to public not occupational or medical exposures. It is noted that ICRP have begun tackling this problem in

ICRP 77 where it is recommended that collective dose be disaggregated into ranges of individual dose over the time period in which it is delivered and cautions the use of estimates of dose and health effects into far future.

With respect to practical difficulties with a threshold for stochastic effects, Prof Clarke highlights the practical aspects of the use of a simple proportional relationship which allows doses within an organ or tissue to be averaged over that organ or tissue, doses received at different times to be added, and doses from one source to be considered independently of the doses from other sources. However he goes on to suggest that a new approach could be considered.

Prof Clarke suggests that there is confusion with the use of terminology such as practices, interventions, dose limits and dose constraints and suggests the possible need to bring occupational, public, medical and accidental dose control into one overall framework.

Prof Clarke offers for consideration the concept of a controllable dose applicable to:
- all controllable sources, artificial, medical, elevated natural, future, or following an actual or potential accident;
- the most exposed individual.

Controllable Dose
- A Controllable Dose is the dose or the sum of doses to an individual from a particular source that can be reasonably be controlled by whatever means.

Based on the individual
- If the risk of harm to the health of the most exposed individual is trivial, then the total risk is trivial – irrespective of how many people are exposed.

He suggests 4 orders of magnitude for dose control:
- a below regulatory concern dose level of 0.03 mSv/y (risk of 10^{-6}/y)
- a public single source dose constraint level of 0.3 mSv/y (risk of 10^{-5}/y)
- an investigation action level of 3 mSv/y (risk of 10^{-4}/y)
- a mandatory action level of 30 mSv/y (risk of 10^{-3}/y)

ARPS Response

In attempting to present a consolidated ARPS view, I have composed and addressed a series of questions and provided ARPS responses based on the body of comments received. These questions were not posed to the ARPS membership except by inference from Prof Clarke's paper.

Question 1

Control of low-level radiation exposure: time for a change?

ARPS Response

Yes. There is a general consensus within ARPS that there is a need for a new approach to the control of low-level radiation exposure. This is mainly based on the unnecessary expenditure of money applied to reduce doses already too small to produce detectable

harm, particularly when the scientific evidence indicates that the risk is either too small to detect or does not exist at all.

Question 2

ICRP Recommendations: need for a change?

ARPS Response

Yes. There is a need to make the recommendations easier to understand and easier to implement. The level of sophistication of the current ICRP recommendations is acknowledged, however, many of the problems and much of the confusion referred to in Prof Clarke's paper result in difficulties in their implementation. The Controllable Dose proposal is unlikely to make implementation easier.

Question 3

Should the ICRP basic principles of justification, optimisation and dose limitation be retained?

ARPS Response

Yes. Particularly as expressed by Prof Clarke in his paper:

- Justification: Do more good than harm.
- Optimisation: Maximise the margin of good over harm.
- Limitation: Individual risk should not be unacceptable.

The concepts of justification, optimisation and dose limitation are logical and well understood and easily communicated to a lay audience. Add ons such as dose constraints and ALARA add to the complexity and degree of difficulty in interpretation and application.

An improved methodology for the optimisation process would be welcomed. The use of dose constraints should be reconsidered.

Question 4

Should occupational and public dose limits be replaced by action levels?

ARPS Response

No. Individual doses should not be allowed to exceed a level that is deemed unacceptable. The Controllable Dose Action Levels proposed have the potential of becoming defacto dose limits. Whether a limit indicates what is safe or unsafe is not an issue. Limits are necessary and can be explained in their context. The issue to be addressed is the control of low doses.

Question 5

Should the Linear No Threshold Dose Response Relationship continue to be used?

ARPS Response

Yes and No. (This question raised the greatest level of controversy.)

Yes. A simple proportional relationship allows doses within an organ or tissue to be averaged over that organ or tissue, doses received at different times to be added, and

doses from one source to be considered independently of the doses from other sources. This is the basis of the effective dose concept, which allows organ or tissue doses to be averaged, tissue weighting factors applied, and the summation of internal and external exposures for the purpose of occupational dose control. This is a powerful practical tool in the system of radiation protection and errs on the side of safety.

No. The validity of the LNT hypothesis is doubtful at doses and dose rates, which are below current dose limits. Its application at these low doses leads to unnecessary expenditure and unnecessary public concern.

Comment. The Controllable Dose proposal does not resolve the LNT hypothesis controversy as the LNT hypothesis continues to be used to relate dose action levels to fatal risk levels.

Question 6

Should the concept of Collective Dose continue to be used?

ARPS Response

Yes and No.

Yes. Used in its correct context with the appropriate caveats, the collective dose concept is a useful analytical and comparative tool.

No. It is currently misapplied to very low doses over large populations and long time spans leading to unnecessary expenditure or the prohibition of otherwise safe projects.

Comment. The issue of misuse of the collective dose concept can be addressed by clearly stated caveats and guidance material on its use. The principle mechanism by which the Controllable Dose proposal addresses this issue is by proposing an action level of 30 microSv/y to the most exposed individual and assuming that if the dose to the most exposed individual in a population is controlled, then the dose to the population as a whole is controlled. Given that we are controlling the risk of stochastic effects here, a low risk to an individual may become significant if applied to a large population over a long period of time. A clear methodology for estimating risk to populations rather than individuals within a population is needed. There is room for innovative thinking here.

Question 7

Should Medical Action Levels be specified?

ARPS Response

No. It is questionable whether dose control should or even can be applied in medical exposures and whether the medical profession would be amenable to such controls. It is suggested that the minimisation of dose to patients is more appropriately achieved via good quality assurance and quality control protocols associated with the various medical treatments, applications and equipment. Medical exposures cannot be controlled as they are determined by clinical requirements. What can be subject to control to a degree is the dose per procedure, and both ICRP and the BSS indicate that reference values should be established by professional bodies or regulatory authorities so that dose per procedure for average patients are bounded. The number of procedures must continue to be largely dictated by patient requirements and clinical indications.

Question 8

Should public, occupational, elevated natural, medical and accident dose control criteria be brought into one overall framework?

ARPS Response

Yes and No

Yes. It would be good to have a consistent approach and framework.

No. We are not comparing like with like, each is internally consistent within its own socio-political context and there is no need to combine them.

Question 9

Are the proposed action levels likely to be acceptable?

ARPS Response

No.

Below regulatory concern level is increased from 10 μSv/y to 30 μSv/y.
Could be challenged by environmentalists.
Public dose limit deleted.
Could be challenged by environmentalists.
Occupational dose limit is relaxed from 20 mSv/y to 30 mSv/y.
Could be challenged by workers.
Upper radon in homes action level increased from 10 mSv/y to 30 mSv/y.
Could be challenged by environmentalists and environmental health officials.

Some individual comments.

- You cannot extrapolate reliably with respect to dose over 4 orders of magnitude below dose levels at which risks have been observed. (Dose Vs Risk is not linear)
- By default the public dose limit could be effectively reduced from 1000 μSv/y to 300 μSv/y
- When looking at populations the average dose to the critical group rather than the dose to the most exposed individual should be considered.
- No stick for regulator – needs limits.
- The unit of radiation dose is a variable depending on circumstances.

Question 10

Should ICRP seek socio-political compromise in its recommendations?

ARPS Response

Yes. ARPS welcomes this opportunity to provide input and congratulates Prof Clarke in his initiatives to open the debate to the wider community. ARPS recognises that the interaction between science and policy here is a complex issue that cannot be addressed simply by a few questions and answers. The diversity of opinion within ARPS reflects this. Clearly the challenges remain and we look forward to fresh ideas and approaches generated by this debate.

7. Contribution of the Netherlands Radiation Protection Society

1. The Society welcomes the opportunity to participate in the discussion about possible future changes in the radiation protection principles. The society installed a working group, in which aspects of the 'controllable dose' proposal were discussed. The points listed below are a reflection of these discussions.
2. The group recognises that the present proposal evolves at a fairly abstract level. Practical implications of the proposed system are not yet clear.
3. The linear no threshold dose-effect relationship is generally accepted as a toll in radiation protection. The Society agrees with the continuation of the use of this relationship for radiation protection purposes in the proposal. The misunderstandings that have arisen from dogmatic ideas about this dose-effect relationship seem to justify a clear statement about its limited scientific value.
4. Regarding the concept of collective dose, the misuse by some is generally known, but there are still cases where collective dose remains a useful quantity. However, the use of collective committed dose integrated over many generations and/or over large populations with extremely small individual doses is generally regarded as misuse and should therefore be abandoned. Other applications of collective dose (e. g. for comparisons of exposures of workers, local populations and medical exposures) are useful and are preferably to be retained.
5. In line with the previous statement the Society welcomes the introduction of a trivial risk level. This concept will probably be of great use in discussions with regulators and the general public.
6. The introduction of a single scale for practices and intervention is seen as an advantage. However, the inclusion of medical exposures within this system is regarded by some as questionable.
7. The introduction of the 'action levels' instead of 'limits' seems not to be useful. Regulators and the general public need a fixed limit for reasons of maintainability and equality of rights. For this reason, a limit on public exposure from all sources together is considered useful.
8. The ICRP has succeeded in establishing a system of radiation protection throughout the whole world with the same limits for exposure of workers and the population. The introduction of the more vague 'action levels', as compared to 'limits', might lead to a diverging level of radiation protection in different countries, depending on what a country may consider as an appropriate action level for each practice. The Society considers this as a considerable disadvantage of the proposal, if the latter situation would occur.
9. The concept of 'justification' remains useful, also in a system. The Society agrees that justification is generally considered at a higher decision level than only by radiation protection experts, but the fact that justification also plays a role outside radiation protection does not justify its abandonment.
10. The idea of a single dose scale is tempting. It is, however, uncertain that this will make the system of radiation protection more transparent and easier to explain to the general public. It is doubtful if it will lead to a greater degree of acceptability of radiation practices in society, especially in situations where the benefit is less clear than is the case for medical applications.

8. Contribution of the Hungarian Radiation Protection Society

Members of the Committee on Radiation Protection of the Hungarian Academy of Sciences and Board members of the Health Physics Section of the Roland Eötvös Physical Society (hereafter: Hungarian experts) have thoroughly studied and discussed the above mentioned papers and their position is the following.

The Hungarian experts

- highly appreciate the review of the history of the development of radiation protection principles and practices;
- agree with the conclusions drawn considering the problems with the present system of protection;
- are convinced that the new concept offers a logical, more consistent and more transparent system; therefore
- support the general concept outlined for future development.

More specifically, the Hungarian experts

- considering the present questions about the health effects of low doses, support the idea that the uncertain risk coefficient should be less emphasised in the regulation scheme;
- are convinced that, in the present situation of strong debates about the rightfulness of the use of the LNT hypothesis, the method offered to avoid this dilemma by the new proposal is very promising;
- welcome the move from the *utility-based* criterion towards an *equity-based* criterion;
- agree with the principle that "*if the risk of harm to the health of the most exposed individual is acceptable, then the total risk is acceptable – irrespective of how many people are exposed*".
- understand the *individual scale of effective dose* and *potential regulatory system* tables (as presented at the OECD) and support their implementation – with all consequences;
- welcome that *Action level* is presented as compared to natural background rather than to risk values, but recommend for consideration to relate *Action level* also to the lowest dose where harmful effects have ever been demonstrated;
- agree with the abolishment of the unlimited quantity of collective dose, and support the introduction of the quantities *workforce dose* and *local dose* – with well-defined uses;
- agree to make more efforts to facilitate the development of environmental protection strategy.

The Hungarian experts think that further elaboration is needed along the lines proposed

- to define constraints for discharges (related to dilution problems);
- to specify the relation of effects and protective actions against *once-off* and *prolonged* exposures more clearly.

Furthermore, the Hungarian experts think that the question of inhomogeneous irradiation, and the appropriateness of the quantity effective dose should be revised.

9. Contribution of the German-Swiss Radiation Protection Society

"Controllable Dose" - Results and Proposals from Discussions within the German-Swiss Radiation Protection Association (FS)

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1. ACTIONS OF THE FS

When the FS received a first copy of the Clarke paper (1) in September 1998, it quickly recognized the relevance of this proposal in the ongoing discussions as a possible way towards an exit from the dead end into which the battle with LNT-model opponents might lead (2). Therefore a German translation (4) was published both in our journal StrahlenschutzPRAXIS and on our web page and distributed together with the English original to all Board members and chairpersons of FS Working Groups and other interested members for detailed analysis and discussion. Several Working Groups and individual members have analyzed the proposal in great detail and depth and have elaborated comments and proposals (5) and in one case even provided a modified and expanded version of the proposal (6) (see 6. below). The Swiss members discussed the proposal in January 2000 at a seminar with Prof. Clarke, organized by the Federal Commission for Radiation Protection (EKS). A discussion of this material with the Board and WG chairpersons is planned for February 2000. A summary will then be presented at IRPA 10 in May. Following the discussions in Hiroshima the FS intends to closely follow the further developments of the proposal and as far as feasible to collaborate and to keep the ball thrown by Roger Clarke rolling towards its goal.

The FS does not intend or attempt to develop a formal unified opinion at this stage. This summary of January 2000 is a snapshot from ongoing discussions and shows highlights and the spread of opinions in a subjective selection and presentation by the author. Both the deadline for submission of the paper and the available space do not allow to present all views and arguments in the desirable detail.

2. GENERAL REACTIONS AND IMPRESSIONS

The author's general impression from all these discussions and comments is that a majority of those who really tried to understand and analyze the proposal reached mainly positive conclusions, but also detected a number of problems, flaws and weaknesses for which they proposed interesting and constructive solutions. There seem to be relatively few who started with a rather negative or conservative attitude or who got fixed to some problem of wording or translating and thus reached rather negative conclusions or even declared that there was no need for a new concept. As always, the attitudes of the "silent majority" which does not dare or want to comment, are difficult to estimate.

Some comments and arguments from German members have to be judged on the background of the special German regulatory and practical situation (still based on ICRP 26, implementation of ICRP 60 / new EC regulations has only started; no provisions for enhanced natural radiation; large problems with residues from uranium mining) which in

many respects differs from that in Switzerland where regulations have been changed according to ICRP 60 and BSS already man years ago (1994).

Terminology

Many readers seem to have difficulties in understanding parts of the text and of the reasoning. This may in part be caused by the German translation (see 6. for proposed improvements in terminology) and - ceterum censeo... - points once more to a general problem - the adequate translation of special or new terms such as "constraint" from English into other major languages -, which leads both to difficulties and to misinterpretations when ICRP recommendations or IAEA standards are translated or are implemented into regulations in other languages. ICRP has members from all major languages and should propose adequate translations of its terminology into the main languages.

Structure of the Proposal

The original Clark paper is too compact and rather difficult to understand (6). There should be a clear separation of:

- problems of the existing radiation protection concept
- misunderstandings in interpretation and application
- different approaches for solutions
- the new concept
- explanations and application of the new concept.

It may also be necessary to discuss separately the new concept in contrast to the present separation of planned protection and intervention, and the derivation of uniform criteria for individual dose for all applications.

Collective Dose

The abolition of collective dose is generally welcomed, but there remains a need for a "group dose" or "team dose" for planning and special purposes, such as comparing the radiation protection efficiency of specific tasks.

3. RESULTS OF ANALYSES

The following summary is mainly drawn from a study in which the FS Working Group on Waste Management (AKE) has summarized several in-depth analyses by individuals and groups (5). Additional opinions and comments will be mentioned both here and in 4. and 5.

The Clarke paper is welcomed as an important step in view of further development of the existing protection criteria.

3.1. Dose Levels

- The four levels - action level, investigation level, constraint, trivial level - should be further characterized in an expanded version of the figure given by Clarke (see Table 1) with the following items:

Name / value in mSv/yr / multiple or fraction of average natural exposure / associated fatal risk (with further explanations) / relation to present criteria and practices / function or application.

- The main comparison should be realistic and made between the levels and the unavoidable average natural radiation exposure. The secondary relation to risk levels is based on a linear dose-effect-relation without lower threshold, but should mainly be used for comparison of risks at higher dose levels with other accepted risks. Both relations together form a basis for the justification of the four dose levels (this justification is different from the justification of new practices).

-> Dose-rate effects must also be considered (medical and occupational areas) and one should show, that the application of the dose levels sufficiently covers short-time high dose-rates.

- Column 5 of Table 1 shows the present criteria and relevant types of application / practices.

- Columns 2 - 5 could be visualized for better acceptance.

3.2. Function or Application of the Dose Levels

- In the last column of Table 1 the function or application of the four dose levels is briefly described.

- For the action level, text and examples should explain, that such doses can only be accepted when the exposed individual has a direct benefit (occupational or medical exposure) or if a reduction of the dose should considerably impair the life-style (intervention, unplanned exposure). In the region 3 to 30 mSv/a optimization is required.

- The region below the investigation level, 3 mSv/a, is in the lower part of the natural exposure. Optimization is indicated, if it is practicable or if there is no benefit for individuals.

- The region below the constraint of 0.3 mSv/a is in the 1-10 percent region of natural exposure and represents additional exposures which are not detectable in the fluctuation of natural exposures. Optimization is not necessary, the single source is already optimized.

- In the trivial region no radiological protection is necessary.

- These applications should be explained in the text with good examples.

- The application of a trivial risk should not allow a release of activity after dilution.

3.3. Justification and Optimization

- The application of the justification of categories of practices and the optimization of individual doses should be explained more clearly. Justification is a fundamental principle and must be maintained, as it is also a part of the European legislation and is important for dealing with residues.

- The abolition of the Collective Dose for use in optimization is welcomed, (also in the majority of other comments from FS members and groups, but some problems, such as cut-off doses, are seen in connection with residue problems). Collective dose is not used in the German or Swiss legislation. On the other hand it is still useful to apply a collective dose for well defined groups of persons with individual doses in the range of a few mSv for the optimization of specific operations, but this should better be called "group dose" or "team dose". In the optimization of operations one should be careful to include the entire relevant chain of operations (it does make little sense to optimize only the conditioning of waste when considerably higher doses occur during final storage of that waste).

3.4. Trivial Dose

- The concept of controllable dose is based on a limitation of the individual dose, and it is explained, that, if the risk from a source for an individual is trivial, then the total risk from this source is trivial and the source is controllable. This reasoning must be extended to the

region of non-trivial doses (professional exposures above 1 mSv/a), and for this the term "sufficiently protected" must be explained. This is closely connected to the question of justification of higher doses for professionally exposed persons. It can be done using two additional arguments:

a) For higher doses, above 10 mSv/a, one should argue with risks, i.e. suggestion of a risk which is also accepted for other professional categories or for the public from other effects of civilization.

b) For doses below 10 mSv/a one should argue with natural radiation exposure, because the assignment of risks will become more problematic and questionable. It is proposed to allow for the total of all groups of persons (or at least for the public and for the professionally exposed persons) a radiation exposure from man-made activities whose average value of ca. 0.3 mSv/a (public) is in the region of the average variation of natural exposures, and which has a similar distribution of values as the natural exposure. In its upper part (> about 1 mSv/a) one would find the major part of the professionally exposed persons and of those parts of the public who are involuntarily exposed.

This split argumentation has the advantage, that the probabilistic risk notion only needs to be used for a small group of persons, while for most of the public and of the professionally exposed persons the arguments are based on the natural exposure and its distribution of values.

Both arguments have in common, that they make radiation protection a part of a broader system of protection by comparison with other risks of civilization and, by comparing with natural exposures, by a link to other concepts of protection (e.g. limitation of concentrations of heavy metals in water). Thus radiation protection would move away from its singular point-of-view, which might improve general acceptance.

(In another discussion group seriously different views regarding the statement "*if the most exposed individual is sufficiently protected, then everyone else is also sufficiently protected…"* (1) and its consequences could not be united and prevented a joint opinion.)

3.5. Summary of the AKE Study:

It should be clearly demonstrated, that the proposed dose levels

- are derived from the level and distribution (variation) of the natural radiation exposures and from comparisons with accepted risk levels,
- are compatible to the state of knowledge on detrimental health effects of ionizing radiation, and
- are no new inventions but a further development of existing recommendations.

It is extremely important to present the developed concept of "controllable dose" to the public in an accessible and understandable way. Also in view of acceptability the central arguments should be presented in the following order:

- Natural radiological situation (level, distribution),
- Generally accepted risk levels, and
- Radiation protection as part of a concept for protection from damaging effects of human activities on a wide basis.

4. COMMENTS FROM SWITZERLAND

This is a short review of comments made by Swiss members, mainly during the EKS seminar with Prof. Clarke:

- The abolition of the unrestricted collective dose is welcomed, but well defined "group doses" with a suitable cut-off and presenting the distribution in space and time remain a useful tool for radiation protection for evaluation of options or for demonstrating state and trends in protection.

- Some legal limits are needed where the individuals have no freedom of choice, but only for precisely measurable quantities. The present limit for the public of 1 mSv/yr could not be abolished without loss of credibility, but it should be interpreted as a guidance level, not a legal limit. A constraint of 0.3 mSv should not become a legal limit because it could make radiation protection unreasonable in specific situations.

- Guidance levels are useful indicators of the order of magnitude of risks.

- Exclusion (of exposures), exemption (of practices) and clearance (of materials) must be clearly defined and properly applied.

- Action levels and investigation levels are already used in applied protection, but set at fractions of legal limits with the aim to avoid violation of limits.

- Make criteria transparent, inform the public and – during development – test understanding of new concepts on members of the public.

- The distinction between practices and interventions is a weak point of the present system, both optimization and intervention reduce doses, but there are no "negative doses".

- A scale of benefits should be developed for comparison with the scale of levels.

- ALARP (as low as reasonably practicable) could be expressed as "do what you can" (DWYC).

- Distinguish between normal and accidental situations and between occupationally exposed persons, patients and members of the public.

- In view of all the problems in understanding the risk notions and the controversies about the LNT-model, would it not be better to completely avoid to use magnitudes of risks as arguments?

- What is "safe" or "unsafe"? A limit is set by convention, not by an absolute magnitude of risk. What is allowed by law or by habit is considered "safe", thus it is "unsafe" to violate a legal limit of exposure, but it is "safe" to exceed an action level and take the prescribed action.

- If the dose to the most exposed individual is calculated in the usual conservative manner, cumulating all kind of rather improbable extreme assumptions, one could again reach a situation where a lot of money is spent for a hypothetical case. Therefore either some reasonable statistical concept should be involved when calculating hypothetical cases, or one should rigorously stick to real situations.

- There are some fears, that a new concept could lower the actual high standard of radiation protection, especially in such fields as decommissioning and waste disposal, and that trivial levels could be misused by intentional dilution of wastes or contaminated foodstuffs.

5. OTHER COMMENTS, PROBLEMS AND PROPOSALS

The following is a collection of comments and proposals from different groups and members of the FS. Lack of space does not allow to present detailed reasoning.

5.1. General Comments, Advantages, Disadvantages

- Some comments criticize the timing and fear negative influence from the discussion of new concepts on the ongoing implementation process of the new EU regulations. But such

fundamental discussions on the international level must start one phase and at least a decennium ahead of the national regulation processes.

- One group (dealing with applied radiation protection) sees no need to replace present concepts because the new proposal does not seem to be more simple or to have more advantages.

5.2. Definition, Terminology

- The adequate translation of "controllable" should express the possibility to measure a dose rather than the necessity to take action above the level (a proposal is made by Krüger, see 6.).

- Missing: a description of what is controllable and what is not.

- The concept should not add a new dose quantity to the too many already existing ones, but it should reduce these quantities to the minimum number needed for application.

5.3. Sources, Individuals, Levels, Limits,

- The principles of the proposal for a single source are no longer valid for the total effects of several sources or of several practices, and for the same source the external and internal exposures may vary by several orders of magnitude depending on different scenarios.

- How shall "non-controllable" sources be considered?

- Do we need the "most exposed individual" which may be difficult to define, or would "any exposed individual" be sufficient?

- Should we use one single investigation level for all practices or different ones for different practices? If only one is used, optimization will be required.

- A critical discussion of the present policy of using limits, action levels, guidance and working levels is welcomed. But experience shows that experts, authorities and courts tend to interpret derived levels as legal limits (especially if the term "limit" is not properly defined and then translated as "legal limit" or "Grenzwert", as is happened with the surface contamination level of fuel transports). Different interpretations may lead to different conclusions and consequences which may deviate from the original purpose of a derived level.

5.4. Comparisons (Risk, Natural Exposures)

- How can the benefit of an individual from a source be defined? Is it a benefit to have a job? Does an expert from a supervising authority also have to tolerate a higher risk? How can the one who benefits from a practice (e.g. the stockholder of a power company) be included in the group of individuals who have to accept higher risks?

- The net benefit of a source would have to comprise its entire duration of use which again would need assumptions and abstractions, so the procedures might become more complicated instead more simple.

- One comment is critical regarding the comparison with fatal risks for the three lower levels which all lie in the region of doses from natural exposures.

- Some comments equalize the application of the same concept to different areas of practices with equalizing the exposures from these practices and think that it would be difficult or impossible to compare benefits and risks.

- A risk level of 10^{-5} might mean for Germany that 1/3 of the drinking water would be unsuitable because of its Radon content.

- Use the general principle that no job is without some risks that are higher than those of the general public.

5.5. Concept, Application

- Is the Clarke proposal only complementary to existing concepts or is it a fundamental change (looking at one specific source in place of the total of many possible and sometimes also unrecognized sources)?

- The proposal applies to many different exposure types and applications, but the one with the highest values is not included: intervention. (A possible solution might be the one chosen in the Swiss regulations (Art. 121 StSV): lifesaving actions may be commanded, if the expected dose is below 250 mSv, for other actions the dose limit for emergency personnel is 50 mSv. Compare to the situation of firemen or rescue teams).

- The "possible solution" section of the proposal contains contradictory dose levels for the public, and one cannot recognize a reasonable philosophy for limiting the doses to all different members of the population (children, adults, workers, intervention teams).

- It seems difficult to express in simple general rules the various ways to respect the dose levels as shown in the examples (but see 6.!).

- Thanks to the single action level there is no more need to maintain the worker categories A and B (special EU and German problem, does not exist in the Swiss regulations).

- The "triviality principle" of the proposal must become a fundamental principle.

- The table proposed by Clarke seems plausible. It would have to become the international standard and to be modified periodically according to the state of knowledge. From this, clear rules for the various practical situations should be derived (see 6.).

- For setting a "tolerance" or "trivial" level there are two possibilities:

a) < 3 mSv/yr, because the average natural exposure is between 1-3 mSv/a without discernible difference of risk,

b) < 0.3 mSv/yr net dose (ambient dose subtracted), but difficulty to determine such a net dose.

The upper dose levels are then based on this lowest level (see 6).

- If internationally accepted dose levels are based on risk considerations which include ALARA and those risks which have been accepted by society, the radiation protection standards can be simplified and unified and will be easier to understand.

5.6. Supervision, Monitoring

- Which control instrument or procedure would allow to detect significant cumulations of doses to an individuum or group?

- A special problem is the progress of measurement techniques towards lower limits of detection, which provokes a trend to lower legal limits! But a feasible measurement is not always a reasonable measurement! -> The requirement for measuring instruments: "lower limit of detection divided by legal limit << 1" should become one of the criteria in the table.

5.7. Acceptance, Positioning of Radiation Protection

- The proposal may lead to better acceptance by the public.

- Legal limits are necessary for acceptance by the public.

- Radiation protection should be put into a general frame, and decision making should consider all effects and consequences, not only the radiological ones.

- The AKI working group agrees with Clark's aim to improve acceptance and avoid misinterpretations by more transparence and by a clear reference to individual risks. They especially welcome a single limit as upper threshold which shall not be exceeded, and action levels below that limit. But they give the proposal only little chance to contribute to an improvement. Intervals in place of limits are unrealistic from a legal view. The irrational public discussions on many health risks show that clear boundaries between dangerous and harmless are requested and that the public does not accept other, more differentiated solutions. The basic problem, the acceptance of risk evaluations, is only semantically shifted to the definition of controllable doses in Clarke's proposal, but also here one finds the notion of "reasonably" whose interpretation has not succeeded in public discussions.

6. A STEP TOWARDS IMPLEMENTATION

Several comments mention problems of the future implementation of the proposal. One member, F.W. Krüger, went one step ahead and remodeled and expanded the Clarke paper with excellent definitions and explanations in a fashion which shows quite clearly how the proposal could be implemented in regulations and in protection practice (6). Krüger also proposes valuable solutions or more precise wording for a number topics mentioned in the AKE study (3. and (5)) and in other comments (4.,5.). Some parts of Krüger's text deal with specific German problems of the present German regulations such as the lack of regulations for exposures from natural sources, these aspects are omitted in this summary. He also splits Clarke's figure into three tables (tables 2-4).

6.1. Definitions

Krüger uses "**controllable radiation exposure**" (German: *beeinflussbare Strahlenexposition*) instead of "controllable dose", with "controllable" in the sense of 'susceptible to influence' (the German translation of "control" has a much more restricted meaning of supervision). Controllable exposure allows a unified determination of the region of applicability and comprises everything that is regulated by the new EU regulations. The same protection principles apply to all controllable exposures, and it is an open list which can be subdivided more finely or can be expanded.

"Controllable dose" is called "*Kenndosis" = "***characteristic dose"** (or simply "dose") and is the highest effective dose of a person from a controllable exposure, all exposure paths and protective actions taken into account.

"Justified doses" (German: *"gerechtfertige Dosen")* is the general term for the four levels (action level, investigation level, constraint, trivial level),

6.2. The New Concept

- **For all controllable exposures the characteristic doses must be restricted by suitable means to reasonably attainable values, the justified doses, which depend upon the individual benefit for the exposed persons.** (Table 2)
- **Protection measures are related to the magnitude of the justified dose.** (Table 3)
- There is a **range of discretion** for fixing justified doses.
- The precautions and measures for restriction of the characteristic doses must be **monitored and supervised** by suitable (differentiated) procedures. If there are

indications for violation of protection or for exceeding justified doses, the **causes have to be determined, evaluated and if necessary eliminated**.

6.3. Explanations

- Justification becomes the fundamental principle of radiation protection.

- Justified doses are not determined by automatism or mathematical formula. A measure of discretion is available which allows to take various factors into consideration, also social and psychological ones and interests of the "stakeholders".

- The requirements of optimization are included. Also when high benefit would justify high doses, the reasonably feasible protection measures must be applied. Justified doses are only acceptable when protective measures have been taken, and these measures must be more comprehensive the higher the doses are.

- Monitoring can comprise assessment of the following quantities:
    - ambient dose or dose-rate
    - activity concentration of radioactive substances in air, water or other samples
    - surface contamination
    - individual exposures (external and internal)
    - other mechanical, electrical or thermal parameters.

- Monitoring follows the same principles for all quantities. There will be several levels for each quantity, the violation of which requires recording, reporting, investigation or restrictive (corrective) actions. Thus the monitoring of dosimetric parameters is not only concentrated on "limits" as dividers between "acceptable" and "unacceptable".

6.4. The Principles of the New System of Protection

- Justification: Doses caused by controllable radiation exposures must be justified by individual benefits.
- Optimization: The real exposures (characteristic doses) must also below justified doses be kept as low as feasible by protective measures which correspond to the exposure level and the state of science and technology.
- Supervision, Monitoring: the observance of the justified doses authorized for a practice and the exposed group of persons and the functioning of the protective measures must be supervised.
- Action: In case of violations of protective measures or justified doses, the causes must be determined, evaluated and if necessary eliminated.

6.5. Comments:

- The system uses the same scientific and technical bases and knowledge as the present one.

- No new or farther reaching radiobiological or technical knowledge is involved.

- No changes in applied radiation protection are necessary.

- The present level of protection remains unchanged (table 4)

- Radiation protection is relieved from theoretical and systematic burdens.

- The system returns to principles which already now are used in practical protection.

6.6. Advantages:

- Radiation protection follows the same principles in all areas of application, also intervention and natural exposures.
- The importance of disputed risk estimates is reduced, they are only tools for setting justified doses, but the main argument is individual benefit.
- The explanation of protective measures does not need to rely on scientifically uncertain or impossible statements (LNT, detriments of low doses, hormesis)
- Decisions on protective measures which involve discretion are recognized as such and need not hide under a disguise of science.

7. HOW TO CONTINUE ?

Our experiences have clearly shown that it will not be sufficient to continue to discuss just the new concept. Such discussions tend to remain somewhat in the clouds and academic. If we want to promote the new concept among radiation protection experts, regulators and interested members of the public, it will be necessary to show very early how the concept could be implemented both in legislation and in the field and how it is able to deal with specific problems. Krüger has made a first interesting attempt, but it relates in many parts to the specific German situation and would have to be "internationalized " and translated into English.

Therefore, once ICRP decides to go ahead with the development of the proposal, the International Organizations - or in a first phase ICRP Committee 4 - should in parallel develop a first draft of new Basic Safety Standards. When the drafts of a new ICRP recommendation and of new BSS will be ready for discussion, IRPA should once more provide the services for a wide consultation among the Associate Societies and the radiation protection community as it was done with the draft of ICRP Publication 60 in 1989.

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FS Officers and Board members, chairpersons and members of FS Working Groups AKE, AKD, AKI, AKP, AKR, AKU, AKURA

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Dose Level	*Multiple / Fraction of average natural Expos.*	*Fatal risk* a^{-1}	*Name of Dose Level*	*Present Criteria* *Areas of Application*	*Function / Handling of Dose Level*
1	2	3	4	5	6
ca. 30	**10**	ca. 10^{-3}	**Action Level**	• Limit for workers (20/50 mSv/a) • Upper action level for Radon concentration • Intervention level for resettlement / evacuation (100/30 mSv) • CT-scan	• **Related to individuum** • Dose should not exceed this level • Acceptance only if benefit for individuum or if dose reduction difficult with considerable impairment of life-style
ca. 3	**1**	ca. 10^{-4}	**Investigation Level**	• Average natural exposure (2.4 mSv/a) • Lower action level for Radon concentration • Dose limit for public (1 mSv/a) • Lower level for simple actions after accident (10 mSv) • Simple X-ray diagnostics (some mSv) • Average profess. exposure (ca. 2 mSv/a)	• **Related to individuum** • Optimization especially when practicable and when no benefit for individuum
ca. 0.3	**0.1**	ca. 10^{-5}	**Con-straint**	• Maximum dose level for single source • Average variation of natural exposure (without Radon)	• **Related to single source** • Maximum dose for individual without direct benefit • Optimization already at source
ca. 0.03	**0.01**	ca. 10^{-6}	**Trivial Dose** with trivial risk	• Exemption level • Clearance level	• **Related to individuum** • No necessity for protective measures

Table 1: Concept of Controllable Dose (from AKE study (5))

Three Tables from Krüger (6):

Individual Benefit	***Justified Dose***	***Examples***
Not given or recognizable	0.03 mSv/a	Exempted materials or products
Exists indirectly, no individual benefit in specific case	0.3 mSv/a	Population near NPP under normal operation
Individual benefit exists	3 mSv/a	Medical diagnostics, prevention of stochastic effects
High individual benefit	30 mSv/a	Radiation worker; living in a house with Radon daughters
Extremely high benefit	> 30 mSv/a	Avoiding resettlements after accident, lifesaving rescue or medical procedure

Table 2: Individual benefit justifies different doses

Justified Dose	***Protection Requirements***	***Examples***
0.03 mSv/a	No special protection measures	
0.3 mSv/a	Protection measures at the source	Retention of effluents
3 mSv/a	Protection by measures at the source and/or simple organizational and technical measures	Ventilation in Radon houses; after accidents: iodine tablets, sheltering
> 30 mSv/a	Protection by a coordinated system of organizational and technical measures	Protection of professionally exposed persons; evacuation after accidents

Table 3: Protection requirements for different justified doses

Fatal Risk	***Dose mSv***	***Proposed System***	***Present Criteria***
10^{-3}	30	Dose should not exceed this level. Approach only when benefit for individual or dose difficult to reduce or avoid.	• Dose limit for workers • Upper level for Radon actions • Intervention level for resettlement • CT-scan
10^{-4}	3	It may be necessary to reduce the dose, especially when no benefit for the individual exists.	• Lower intervention level for sheltering • Lower Radon action level • Average natural background • Level for diagnostics
10^{-5}	0.3	Maximum dose for individuum without direct benefit from the single source.	• Maximum constraint for single source • Variation of natural background (without Radon)
10^{-6}	0.03	Trivial risk for individuum	• Exemption level • Clearance level

Table 4: Comparison of present and new criteria

10. Contribution of the UK Radiation Protection Society

Controllable Dose: SRP International Committee Working Party Summary Report

Preface

The following paper represents the collated views and opinions, and an analysis of the questionnaire responses, derived from a consultation exercise carried out in the latter half of 1999 by the International Committee of the SRP. It does not purport to be either a consensus or a representative view from the UK radiation protection community; rather its value is in the range and quality of ideas and thoughts that the consideration of controllable dose has provided. The document therefore entirely meets its purpose in providing a basis and catalyst for further discussion of the subject, and to act as key briefing material for the SRP delegates in the forthcoming IRPA 10 meeting at which "controllable dose" will be an important topic for debate.

1. Introduction

Following the publication ‘Control of low-level radiation exposure: time for a change?’, distributed by the International Radiation Protection Association (IRPA) and subsequently modified by the author, Roger Clarke, and published in the Journal of Radiological Protection (R Clarke 1999 JRP 19 (2) 107–15), the Society for Radiological Protection (SRP) formed a Working Party (WP) whose remit is to discuss the issues arising from the paper and to prepare a response on behalf of the SRP which is the IRPA Associate Society. The WP considered the paper in great detail and prepared a questionnaire on the 33 aspects considered most important. The questionnaire is attached as appendix 1, together with a compilation of the responses received. Appendix 2 contains additional proffered comment. The questionnaire was sent to approximately 1500 UK international members. Although there was only a 6% response, the views expressed were wide-ranging, reflecting the broad professional interests, industrial, medical, academic, research and regulatory, of the international membership. This paper is a distillation of the responses together with the views of the SRP Council and its partner societies in the UK. Incidentally, the questionnaire has been adopted by other countries as a tool to help guide their debate.

2. Discussion

The opportunity to discuss and debate the concept of controllable dose at a very early stage, before it could possibly become International Commission on Radiological Protection (ICRP) policy, was welcomed by the membership. The subject matter was disseminated throughout the UK radiation protection community via the SRP to all its IRPA members who are known as the international members. In this way, the views of all interested parties were sought. There was a suggestion in the WP that issues relating to public exposure should be the subject of public consultation by seeking the views of, for example, non-governmental organisations, trade unions, Friends of the Earth and Greenpeace, etc. After due reflection, it was decided not to follow this suggestion as these organisations would have access to other routes for

comment (the key documents have been posted on the public side of the SRP website) and this response should be from the radiation protection community.

3. The current ICRP approach

The present ICRP approach to radiation protection is, in the main, well accepted and functional in most situations. It is also recognised that the current system is rather complicated and has given rise to some difficulties in communication between the 'radiation protection experts' and 'the public'. Public perception of ionising radiation is tending towards the view that it is 'unsafe at any dose', though a double standard exists in public perception, for example with the 'safe' use of medical radiation. The new concept tries to simplify the present approach, making it more understandable to non-experts. However, it does not address the public's inherent fear of radiation. Much thought will be required should the concept be introduced to the public. The interpretation of the radiation protection professional will undoubtedly be very different from that of a member of the public.
One of the advantages of the current system is that it is very comprehensive and covers all types of exposure, i.e. public, occupational, medical and emergency situations. However, because of its wide scope, some types of exposure do not fit as well as others. Consider public exposure. The public is concerned about doses of a few μSv from radioactive discharges, even if radiation protection experts advise otherwise. Limits are often seen as the boundary between that which is considered to be 'safe' and that which is considered to be 'unsafe'. The new dose concept, as described may be explained in terms of acceptable risk or in fractions or multiples of the natural background. This is considered to make it more understandable to individuals outside the radiation protection profession, but there are public misconceptions in the understanding of 'natural background' radiation.

4. The new approach: justification

The initial scientific overview presented by Professor Clarke in the discussion paper is a very useful statement of the present issues and concerns. The arguments to support his suggestion of a change in philosophy on how to deal with low-level radiation hazards are very clear. The practicalities do, however, raise some concerns. Indeed the term 'controllable dose' is itself misleading as it pre-empts the question of what to do about doses which are 'outside control'. Some alternatives have been suggested (see appendix 2), but none of these is yet perfect. Perhaps the simple solution would be to turn the terminology around and call the concept 'consistent dose control' or just 'dose control'. It would also seem inappropriate to specify maximum dose levels, which would be applied uniformly across the whole population. Action levels may be more appropriate as these could be exceeded but only on the basis of individual justification, for example in medical exposures.
Although high-dose situations are considered to be outside the scope of the proposed scheme, there is a strong feeling that such situations should still be controlled and should therefore be integrated within the scheme. In the medical field, the risks of even moderate levels of radiation are clearly much less significant to patients with advanced malignant disease than to healthy members of the population or children. Patients with benign disease could receive medical exposures considerably greater than the proposed maximum annual dose of 20–30 mSv, for example with justifiably repeated CT scans for pancreatitis or during certain nuclear medicine procedures. However, one view expressed was that no medical exposures should be included in the new concept of controllable dose. A single upper-bound control level, whilst

perhaps simplifying regulation in the eyes of non-specialists, could compromise the ability of the medical profession to use ionising radiation wisely when the clinical situation would appear to justify its use. Justification for medical radiation exposure is clearly of value where there is a need to balance the risk of adverse consequences from exposure to ionising radiation with the risk of adverse events if the procedure is not performed. Case by case justification might also have a legitimate role in some optimisation exercises.
On the wider issue of justification, there is a strong case for accepting that the principle itself is sound, but that in reality issues concerned with radiation protection will only ever comprise a small input to the overall judgement. Hence, it is important that any new restatement of philosophy must position the concept of justification very carefully, ensuring alignment with society's approach to other hazards and, in particular, encouraging its direct application in the medical field.

5. The individual dose scale and guidance levels

The concept of a unified contextual scale for individual dose is fully supported. This scale is broadly set out in decade ranges, covering 'serious' (above about 30 mSv at which action or individual justification would be required) to 'trivial' (less than about 0.03 mSv which could be safely ignored). The proposed approach, based on multiples of three, sets the right tone, but would benefit from more flexibility at the margins (is 35 mSv in certain limited medical exposures really 'serious'?). In this sense it may be helpful to build on the range of natural background exposures taken at a national level—3 mSv per annum may be the most representative single figure, but plus or minus 50% on this is by no means uncommon. The link between the dose scale and natural background in general terms is seen as a positive communication aid and should be strengthened.
The introduction of guidance levels, 'trivial, investigation and action', is seen as a useful tool in eliminating confusion by removing the need to distinguish between occupational practices and interventions after a radiation incident. The use of 'action levels' provides a common understanding of the significance of dose levels rather than the present limits, which are often misunderstood and frequently perceived by the public as the boundary between 'safe' and 'unsafe'. However, defining a trivial radiation level below which the system of radiation protection is no longer needed does not necessarily mean that a public dose limit becomes unnecessary. In addition it is also important to recognise that perceptions of 'safe' and 'trivial', etc, are intimately linked to the nature of the benefit received in return for the radiation exposure. Further consideration should be given to how best to integrate the concept of benefit.

6. Optimisation, ALARP and collective dose

The new approach helpfully retains the concept of optimisation, and the Euratom Directives which follow the earlier ICRP recommendations clearly identify the need to implement more fully the principle of ALARP. Virtually all practitioners regard optimisation/ALARP as the key component in practical radiation protection and would wish for this concept to be given even greater prominence. The avoidance of the use of 'constraints' is seen as a welcome step forward in radiation protection, although it is acknowledged that constraints are considered by some to be a useful design tool for planning purposes to ensure future exposures will be below the dose limit.
The principle on which the new concept is based is 'if the risk of harm to the health of the most exposed individual is trivial, then the total risk is trivial—irrespective of how many

people are exposed'. Whilst the current ICRP trend is to rely less on the use of collective dose in the justification and optimisation of radiation protection, collective dose does have some value as a marker in occupational exposure. However, eliminating the need for collective dose at trivial levels is seen as helpful with regard to public exposures, although the concept of considering a 'local dose' which identifies the number of persons exposed locally to a source above a trivial level is worth further thought. Some concern was expressed as to the ethics involved in not considering collective dose from decommissioning and discharge practices. It was strongly suggested that this could lead to intentional dilution and dispersion of contaminated materials in order to achieve levels of contamination resulting in trivial individual doses.

7. Regulation

The introduction of any new approach in the field of radiation protection gives rise to concern regarding its translation into regulations, especially by those with direct responsibility for regulation. However, the new concept offers a way forward to integrate radiation protection for all radiation sources and risks from all sources, and it is agreed in the main that ICRP, whilst having some concern for practicalities, should operate at a philosophical level and not place too much consideration on how its recommendations would be converted into regulations. The paper clearly applies a good link between risk and tolerability of risk, and is seen to be broadly consistent with the approach taken to risk in other industries. A framework based on action levels and investigation levels may provide a more flexible basis for an integrated approach to protection, but regulators are likely to want to maintain the option to set dose limits for some time to come. There is a vagueness around action levels which may complicate or inhibit effective regulation of occupational and related exposures, but, more importantly, workers and the public are likely to be highly wary of the removal of dose limits which are perceived as being the ultimate backstop for their protection. The individual risk based approach could also be consistent with the developing envi-ronmental protection philosophy. The ICRP statement 'protection of man will assure suffi-cient protection of the environment' is increasingly being challenged as not being sufficiently founded in science. The philosophy of controllable dose is focused on the individual. If the in-dividual is sufficiently protected from a single source, then that is considered a sufficient basis for the control of the source. A similar approach could be developed in parallel for other biota. As controllable dose relates to a specific source, the question arises as to how we would deal with 'multiple sources'. Given that if the dose from each individual source is controlled, there does not appear to be any reason why the doses from each source need to be added; however, clear reasons for this approach are needed. One area of potential confusion where clarification would be welcome is the unified consideration of annual doses on one hand (e.g. occupational exposure or natural background) and single event exposures on the other (e.g. medical exposures). It would seem that these are linked because of the common nature of the decision processes, but further explanation and discussion would be advantageous.

8. Conclusions

The object of this open debate is to compare the advantages and disadvantages of the present system with those presented by Professor Clarke's concept. The concept offers a way forward for a consistent radiation protection policy for all radiation sources. However, great care will be needed, both by regulators and the profession as a whole, in the presentation of this

concept to the public, and further consultation and discussion on this would be welcomed. It should also be stressed that the present system of radiation protection is generally well understood and assures adequate protection of workers and the public against ionising radiation. Any changes should not be immediate, as a period of stability is required, especially in view of the implementation of the new Ionising Radiations Regulations (IRRs) in the UK.

Working Party Members
Robert H Corbett, Chairman, SRP International Committee
Roger Coates, Secretary, SRP International Committee
Christine Edwards, Member, SRP International Committee
Tony Bandle, Member, SRP International Committee
Penny Allisy-Roberts, Member, SRP International Committee

11. Contribution of the US Health Physics Society

CONTROLLABLE DOSE

A WHITE PAPER ISSUED BY THE SCIENTIFIC & PUBLIC ISSUES COMMITTEE

INTRODUCTION

Professor Roger H. Clarke is proposing changes in some fundamental principles in the system for radiation protection. Professor Clarke is seeking a broad input to his proposal for consideration by the International Commission on Radiological Protection (ICRP). His original proposal, which was distributed internationally to radiation protection societies and associations, has continued to evolve as he has received input and comments. The Health Physics Society (HPS) is pleased to be part of this dialogue. Professor Clarke's proposal will be discussed further by the international radiation-protection community at the 10 th Conference of the International Radiological Protection Association (IRPA) in Hiroshima, Japan. The Scientific and Public Issues Committee of the HPS has developed this White Paper in accordance with its responsibility to prepare impartial scientific and technical statements representing the Society's position. This paper is specifically intended for use by the Society delegation to the IRPA Conference.

POINTS RELATED TO THE PRINCIPLES OF A RADIATION-PROTECTION SYSTEM ADDRESSED IN PROFESSOR CLARKE'S PROPOSAL

The HPS has chosen to provide comments on what appear to be several underlying points incorporated in Professor Clarke's proposal which are related to a radiation-protection system. These points are:

1. Reason for Change
2. Individual dose criterion
3. Combining all "controllable" sources of exposure
4. Differentiation between practices and intervention
5. Controllable Dose Levels and Terminology

REASON FOR CHANGE

The HPS believes that proposals for changes in the system of radiation protection must have a clearly identified reason for the change. Professor Clarke's reason for making his proposal is to improve public understanding of radiation protection standards.

We believe the problem of public understanding is related to unwarranted fears and perceived risks at low radiation doses. The HPS believes there is a way to address this problem without introducing an entirely new dose term. We believe improved public understanding and acceptance of radiation-protection standards will be accomplished by:

(1) controlling individual dose, irrespective of how many people are exposed, combined with;
(2) not associating quantitative risk estimates with individual doses below 50 mSv in one year or a lifetime dose of 100 mSv above background radiation. (See the HPS Position Statement "Radiation Risk in Perspective" January 1996).

In the context of Professor Clarke's proposal, we support his statement of the principle for the protection philosophy for controllable dose, but we believe his use of "Fatal Risk" on his Controllable Dose Chart is inappropriate.

INDIVIDUAL DOSE CRITERION

The HPS supports a radiation-protection system that is based on protection of the individual and opposes the use of collective dose in setting radiation safety standards.

This is consistent with some aspects of Professor Clarke's proposal.

COMBINING ALL "CONTROLLABLE" SOURCES OF EXPOSURE

The HPS agrees there is some potential benefit in linking exposures from all sources for simplifying the public's understanding of radiation-protection systems. Linking exposure limits, or upper bounds, to background radiation levels may be simple for the public to understand if presented properly since everyone is exposed to background radiation. With the disassociation of risk-based terminology from occupational and environmental levels of exposure, as discussed above, comparison to variations in background could be very useful in putting radiation-protection quantities in perspective. Proper linkage may also get us out of the often indefensible position of controlling public doses from nuclear technologies while seemingly ignoring larger doses from natural and medical sources.

However, the HPS believes there is a need to differentiate between occupational, public, and medical exposures in a radiation-protection system that sets upper bounds on these exposures. The potential risk and potential benefit must be considered and these are different in the case of occupational, public, and medical exposures, even if they can not be accurately quantified. The HPS believes occupational, public, and medical exposures should be evaluated and controlled separately. Furthermore, all medical exposures should be excluded from any system that would set, or imply an upper bound to the exposure an individual receives from prescribed medical procedures.

DIFFERENTIATION BETWEEN PRACTICES AND INTERVENTION

Professor Clarke states that with his proposal "There would be considerable scope for a simplification of the system of protection and remove confusion by not distinguishing between practices and intervention." Professor Clarke uses these terms like the ICRP in which a practice is the introduction of a radiation source of exposure and an intervention is the initiation of a protective action for an existing source of exposure.

The HPS does not believe that the differentiation of radiation protection actions as related to practices or interventions makes any difference in the public's understanding of these actions, at least in the United States, and is not, therefore, an important consideration for accomplishing the purpose of the proposed changes.

CONTROLLABLE DOSE LEVELS AND TERMINOLOGY

Professor Clarke proposes working “toward a single maximum level of controllable dose. Doses significantly above this level would only occur in uncontrolled accident situations or in life-saving medical procedures. It may be that rather than referring to this value as a limit, the term ‘action level’ should be used.”

Although the HPS agrees with Professor Clarke that a “limit” can be, and often is, misunderstood, the reality of implementing a radiation-safety program within a formal regulatory framework requires there be a value that is singular, and unequivocal that represents a dose which should be prevented by responsible control and one above which responsible control has been exceeded.

The HPS supports a system of radiation protection that has; 1) “an upper bound of acceptable risk,” such as a “Regulatory Limit” (i.e., a term that does not imply a boundary between safe and unsafe conditions), and 2) “Investigation Levels” below this upper bound that identify when radiation-protection actions should be taken (i.e., ALARA investigation levels).

The HPS believes that the proposed “Trivial Risk” level of a few tens of micro-Sieverts is so low that it carries no concern for adverse health effects and should not, therefore, be incorporated into a radiation-protection system. Furthermore, the HPS believes the lowest ALARA investigation level should be 1 mSv per year.

CONCLUSION

The HPS appreciates the initiation of an international discussion on the current fundamental principles of our radiation-protection system with an interest in developing a system that is both understandable by, and protective of, members of the public and occupational radiation workers. We believe the most important aspect in achieving this goal is a risk-informed, dose-based system with elimination of quantified risk estimates and risk-based terminology at occupational and environmental dose levels.

12. Contribution of the South African Radiation Protection Society

Controllable Dose - A South African Perspective

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INTRODUCTION

The Southern African Radiation Protection Co-ordinating Body (SARPCOB) represents radiation protection practitioners involved in nuclear fuel cycle facilities, the medical and industrial fields as well as a large variety of mining and minerals processing activities. A number of workshops were arranged during the second half of 1999 to solicit the views of these practitioners on the 'Controllable Dose' concept and this paper summarizes those views. The workshops did not specifically attempt to establish a consensus position as it was realised from the outset that differing views prevailed. Nevertheless, agreement was recorded in a number of areas particularly in identifying the need to have a relatively straightforward system of radiation protection that was consistent and coherent and that could be effectively applied and subject to regulatory control.

The paper starts with views on the current system followed by a general discussion on the 'Controllable Dose' concept, thoughts about specific principles contained in the reference paper on 'Controllable Dose' and, in conclusion, some recommendations.

THE CURRENT SYSTEM OF RADIATION PROTECTION

The paper on Controllable Dose highlights certain problems with the application of the current system of radiological protection recommended by the ICRP. There was general agreement among SARPCOB members with the analysis presented in the paper.

The financial implications of adherence to the linear no-threshold theory (LNT) and the difficulty of dealing with situations that do not easily fall into the current definitions of practice and intervention in particular were seen by many as being problematic for the South African situation with its substantial mining and minerals processing operations that involve moderately elevated levels of naturally occurring radionuclides and that have been carried on in some cases for more than a century.

The LNT Issue

In the view of a number of members many of the difficulties with the current system stem from the fact that it is based on the LNT. In South Africa , it has been estimated that the mining and minerals processing industry has generated altogether about 9 billion tons of residues with moderately elevated levels of radioactivity, and these are being added to at a rate of more than 300 million tons per year. The earlier mining operations especially have become centres of subsequent urban growth, with the result that some of the residue deposits have become closely surrounded by townships and factories. Some residues have been

removed for reprocessing, leaving open land that is in great demand for industrial and residential purposes, but which contain residual contamination.

There are no mines in South Africa in which uranium is exploited as a primary product, although a limited amount of uranium is still produced as a by-product, mainly of gold. The levels of radioactivity in gold mine residue deposits are typically between 5 and 20 times lower than those associated with former low-grade uranium mining and milling operations in Germany, the USA and Canada. Overall, it is estimated that about 85% of South African residues with elevated levels of radioactivity have an alpha activity of less than 5 or 6 Bq/g. Notwithstanding this, there could be exposure pathways that still give rise to significant radiation doses. The degree of risk that this residual material is consequently deemed to represent to the public, and thus the financial implication of providing adequate protection or remediation, is therefore critically dependent on whether a linear dose-response relationship is assumed to hold at low dose levels. .

In the absence of evidence from epidemiological studies or by complementary molecular biology studies, of a dose-effect relationship at doses below 50 to 100 mSv, judgement has to be applied. Some members are concerned that in such situations, erring too much on the side of caution could lead to the expenditure of vast sums of money with no tangible benefit.

Practices and Interventions

Another problem that arises in connection with these mineral residue deposits is associated the distinction between practices and interventions. Consider, for example, a gold mine tailings dam containing tens of millions of tons of slightly radioactive material. The dam might be 40 years old and no longer in use, but the mine on which it is situated is still in operation and has in the meantime become subject to a regulatory control regime that requires compliance with current ICRP recommendations.

The tailings dam may have been poorly sited and designed with respect to current standards controlling contaminant migration into the environment, but clearly it is not possible to turn the clock back. One argument could be that the opportunity for the prospective consideration normally associated with practices has been lost. However, it could be further argued that the practice must be simply be modified to achieve compliance with requirements for practices, but this might be unreasonably onerous in some circumstances.

Alternatively, the tailings dam (but not the mine itself) could be deemed to be subject to the principles of intervention. Remedial action, if any, would be determined on the basis of optimization but without reference to dose limits.

Such arguments become even more complicated when the tailings dam is still operational. In such situations the opportunity for prospective consideration on siting is lost, but prospective consideration on design may still be possible.

Apart from the difficulties associated with the classification of an activity as a practice or intervention, the definition of discrete sources or practices is also often problematic. Mining and minerals processing operations give rise to many exposure pathways for public exposure varying from discharge of mine process water and up-cast ventilation, through airborne dispersion of mine tailings and radon emanations, migration into ground water of activity from waste rock and tailings piles to intrusion and material diversion scenarios. Combined with the start up and closure of mining operations, the re-working of old tailings and amalgamation and splitting of operations the task of delineating the source and indeed the regulated entity could become extremely difficult.

Current ICRP standards do not provide clear guidance on how to deal with situations such as this, and some of our members felt that it is likely that under the current framework no such guidance could be offered other than to say that each case should be evaluated on its merits. Again, judgement has to be applied which some believed, depending on the degree of caution, could result in a massive financial burden on the operation with no tangible benefit.

Collective Dose

The use of collective dose is not specifically identified as being a problem with the current approach although, notably, it does not form part of the proposed 'Controllable Dose' concept. The way in which collective dose is used by some, is seen by our members as problematic. In the absence of definitive evidence of health effects at low doses, there is general concern amongst our members that the multiplication of low doses by large numbers of persons and over long time periods is creating exaggerated estimates of risk, especially when used to predict numbers of fatalities attributable to low levels of radiation exposure. A number of our members believed such a concern made the definition of a threshold appear attractive.

Positive Aspects of the Current System

Notwithstanding the problems described above, and the view that they have to be addressed, members also recognized that the current system has been widely accepted and adopted. Whilst in applying the system difficulties have been identified, some members felt that it would be more appropriate to more fully understanding these difficulties and modify the existing system to accommodate them. In this regard, the statement that the proposed scheme *"may be complementary to, rather than a fundamental change in, the Commission's system of protection and may be of use in its application"* is generally supported.

GENERAL OBSERVATIONS ON THE 'CONTROLLABLE DOSE' PAPER

In general, members see the proposed system of protection as a positive step towards overcoming the difficulties that have been identified with the current system. Although some members are not convinced that the proposed system is simpler in concept, all members agree that it is an attempt to simplify the system and that it has the makings of a more unified and straightforward approach.

On the other hand, it is widely believed that the proposed system as it stands will not fully resolve all the issues of concern, that it might be difficult to implement, and that considerable further thought and development will therefore be needed to clarify and elaborate on certain aspects. Some members are not yet convinced that there is any clear advantage over the current system, since it could simply lead to the exchange of one set of problems or questions for another.

In considering the extent to which the 'Controllable Dose' concept could succeed in addressing the problems identified with the current system, members have expressed technical concerns in two general areas:

i) The proposal does not adequately address the control of low doses, specifically those below the proposed Investigation Level of around 3 mSv per year. The proposal as it stands will not avoid arguments about the LNT, although it is recognized that some elements of the proposed system could address concerns in this regard.

ii) Although the proposed system avoids having to draw the sometimes difficult distinction between practices and interventions, it introduces other judgemental factors that will be

equally difficult to deal with unless more explicit guidance is developed. These factors - defining the "benefit to the individual" and the "ease of preventing or reducing the dose" - take on a crucial significance in establishing the extent to which doses should be controlled (i.e. the allowable levels for a particular situation).

There is also concern that the 'Controllable Dose' concept, regardless of its technical merit, could be difficult to translate into precise and explicit regulatory requirements - probably more difficult than for the current system. Moreover, it is not clear to our members how exactly the new system will complement the present system rather than replace it.

Some members expressed concern over what was perceived to be an arbitrary and imprecise setting of numerical values in the proposed system. Legal systems are widely based on the adoption of limiting values and whilst scientific uncertainties are accepted to exist, some members believed that the greatest extent of precision and rigour should be applied along with the best scientific judgement to the process of establishing limits. Caution was expressed that the credibility of the profession could be undermined by an arbitrary and imprecise setting of the numbers.

Considering the effort involved in revising safety standards worldwide, and the complex question of public acceptance, it has been suggested by some members that the best course of action might be rather to use the proposed concepts to modify and improve the present system. Others believe that, with further development, the proposed system can provide a workable and much-improved framework for radiation protection, and that the effort involved would be worthwhile.

SPECIFIC VIEWS ON PRINCIPLES RELATED TO THE PROPOSED SYSTEM

The Term 'Controllable Dose'

Members observed that confusion could arise about the term 'Controllable Dose'. From the proposed definition of controllable dose:

> *"A Controllable Dose is the dose or sum of the doses to an individual from a particular source that can reasonably be controlled by whatever means"*

it would appear that, except for doses that are clearly not amenable to control such as cosmic rays at ground level, <u>all</u> other doses from a particular source to the individual are regarded as controllable to a greater or lesser extent. Some interpreted this such that the issue is not whether a dose is controllable; it is rather a question of "what is the level of significance of the controllable dose?" (a quantity that according to the proposal would depend not just on the magnitude of the dose but also on the benefit to the individual and the ease of reducing or preventing the dose). Others, who saw the question whether a dose is controllable as an issue, were concerned that the question whether an activity is a practice or an intervention under the current system will simply be replaced by the question whether the dose from a source is controllable or not under the proposed system. The latter was highlighted by the fact that there was no consensus amongst our members on the proposal that high terrestrial levels of natural exposure should be regarded as amenable to control and thus included within the definition of Controllable Dose.

However, some members felt that, despite the explicit definition of 'Controllable Dose', the use of the term "controllable" (to the extent of including it even in the title of the proposed system of protection) could cause confusion by creating the impression that the whole

concept was about whether doses could be controlled or not, and this in turn would lead to a need for the term "controllable" to be more precisely defined or quantified.

Furthermore, it was noted that the proposal to dispense with the use of the term "dose limits" in favour of "action levels" and "investigation levels" could imply that the concept was more about the management of doses rather than their control. The term 'manageable dose' was for the same reason suggested as an alternative to the term controllable dose. Those in favour of this term felt that it will more clearly express the capability of human beings to control the risks and will also allow for easier incorporation in an overall risk management system.

Collective versus Individual Dose

Although the formal and quantitative inclusion of collective dose in a regulatory system was not favoured, members were divided about the role that collective dose should play in the radiation protection system. There were members that agreed with the proposal that collective dose should play no role at all in the proposed new system, while others felt that it had a role in the optimization of protection when comparing protection options.

It was noted that that the proposed system was based only on individual doses and that further guidance will be needed on the application of the principles of justification and optimization. Since, in occupational and public health generally, collective risks are commonly used in such evaluations, some members would rather see the outcome of this further guidance development before agreeing that collective dose can be dispensed with entirely.

To avoid the inappropriate estimation of harmful effects through the multiplication of very small doses with very large numbers of people, some members saw merit in the definition of a generic level of individual dose below which further optimization is not necessary and the application of collective dose would hence not be an issue.

The Regime of Controllable Doses

The proposed regime of controllable doses characterized by an upper level of acceptability (the 'limit' or Action Level) and intermediate Investigation Levels was generally seen as a better alternative to a system of widely differing dose limits and other forms of dose restriction, the logic of which is not readily understood by the public.

Problems were foreseen, however, in applying such a system because the regulatory concept of "limits" has become firmly entrenched in legal systems and society generally.

The setting of an upper-bound limit or Action Level at a figure of around 30 mSv had some support, although a way will have to be found of dealing with arguments stemming from the "rounding" up or down that this represents when viewed against the current system. For instance, 30 mSv represents a 50% increase in the annual-average occupational dose limit, while at the same time it represents a 40% reduction in the lower level of averted dose above which evacuation is recommended after an accident. It would also question the status of the 50 mSv single year limit possibly implying this should be revised to 75 mSv.

There was some discomfort with the fact that certain radiation exposures above the Action Level (exposures in radiotherapy and interventional radiology) were nevertheless regarded as acceptable and thus did not fit neatly into the proposed system. However, no suggestion could be made as to how to deal with such situations other than to accept them as anomalies.

Moving down the scale, there was some support for the statement that:

> *"At levels of controllable dose of the order of a few millisieverts per year, the exposures should not be of great concern from the point of view of an individual's health"*

and for the philosophy of accordingly treating the band between ~3 mSv and ~30 mSv as a region in which it becomes increasingly desirable to reduce or prevent the dose depending on the benefit to the individual and practicability.

As mentioned previously, however, the translation of this philosophical concept into hard regulatory guidance will be a challenging task.

The proposals on how to deal with doses below a few mSv were a source of major concerns among many of our members, and these are dealt with in more detail below.

The Control of Exposures Giving Rise to Low Doses

Situations giving rise to doses of the order of a few tens or hundreds of microSv are without doubt the area of greatest concern and controversy. A wide range of issues are involved, many of which are interrelated:

- the concept of trivial dose and its impact on what should be included in, or may be removed from, the system of regulatory control;
- consideration of natural background exposures in establishing appropriate measures of protection;
- the future role, if any, of the existing dose limit to the public based on exposures from all relevant sources;
- the setting of source-related public dose constraints, and their function in a regulatory system;
- the LNT debate;
- exposures to natural radiation sources; and
- exposures to radon in particular.

Some members felt strongly that the 'Controllable Dose' concept provides a valuable opportunity (and possibly the only opportunity in the foreseeable future) for addressing serious concerns associated with the abovementioned issues, but that little or no attempt had been made to make use of this opportunity. Their views on this matter are summarized below:

i) Trivial individual dose

Doses to individuals and the resulting harmful effects are both stochastic in nature (due to variations in background radiation) and subject to statistical variation (due to variations in biological susceptibility of individuals as reflected in the distribution of the overall background cancer incidence rate against which the significance of the radiation-induced cancer incidence rate must be evaluated). Because of the uncertainties caused by these variations, no statistically valid decision can be made on whether radiation doses below a certain "critical level" will result in harmful effects[1]. Consideration only of the variation in background levels suggests a critical level in the range 100 to 1000 microSv/a. If the variation in biological susceptibility of human tissue is added, the critical level may run even

[1] Robertson, P L, Carlson, R D. Determining the lower limit of detection for personnel dosimeter systems, Health Phys. 62(1):2-9; 1992

into the lower mSv/a range. It was suggested that any new system should address this matter and that future research should focus more on the issue what is significant and insignificant in terms of these uncertainties rather whether the LNT is valid or not. Other members, however, cautioned that this could lead to different 'acceptable' levels in different parts of the world and that the associated implications for international trade should be taken into account e.g. when clearance levels are determined for bulk materials.

A further major uncertainty, of course, is the dose-response relationship at low doses, i.e. the validity or otherwise of linearity. However, there does not seem to be any end in sight to the international debate on this matter, and there are serious doubts as to whether this will be resolved by further research in the near future.

Against this background, some members expressed strong reservations about the use of an individual dose of a few tens of microsieverts per year as the sole basis for decisions on exemption and clearance. Aside from the contention that doses of this order have little statistical significance, some members felt that the retention of such a precise (yet somewhat arbitrary) criterion for decision-making goes against the spirit of the 'Controllable Dose' concept which, for low doses, should be providing more scope for reasoned judgement. These members believed that an example of the need for flexibility in this regard can be found in the most recent views emerging from the European 'Article 31 Group of Experts' on exemption and clearance criteria for materials with regard to their content of naturally occurring radionuclides. Because of important practical considerations, a level of 0.3 mSv/a is being proposed as the basis for exemption and clearance of such material[2]. In counter-argument, the concern was expressed that this flexibility and possible associated differences between materials from the nuclear and, for example, mining and minerals processing industries could cause major practical difficulties in international trade and public relations.

ii) Exposures to natural sources

Exposures to natural sources, which give rise to doses of up a few mSv's per year (although often still significant from a protection point of view), are at the centre of many concerns with respect to the proposed system of protection. There is a strong feeling that such exposures have not been sufficiently taken into account in the development of the 'Controllable Dose' concept. This is despite the concept being seen by some members as providing an excellent basis for dealing with the practical realities associated with materials containing naturally occurring radionuclides that are not readily accommodated in the current system of protection.

The first real indication of serious consideration being given to this kind of material in a system of protection can be found in the new European Basic Safety Standards[3]. In a description of the new Directive[4] it is stated that:

> *"……the Directive applies to:*
> - *Practices, which include ……..*

[2] Concepts of Exemption and Clearance. Working Party of the Article 31 Group of Experts (draft, May 1999)
[3] Council Directive 96/29/Euratom of 13 May 1996 laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. Official Journal of the European Communities, L159, Vol. 39, 29 June 1996
[4] Ulback, K. The European approach: European directives on radiation protection. Proc. IAEA/WHO Conference on Low doses of Ionizing Radiation: Biological Effects and Regulatory Control, Seville, 17-21 Nov 1997

- *Intervention, which includes ……*
- *Work Activities with natural radiation sources, which is a new concept defined to take account of significant exposures to natural radiation sources that can lie in the grey area between practices and intervention."*

The description of the Directive goes on to state how significant exposures to natural sources are treated quite separately from pure practices and interventions:

> *"All requirements on exposure to natural sources ……. are given in Title VII (of the Directive) …….*
> *…….the Member State must monitor the exposure in an appropriate way and impose all or part of the requirements in the Directive for practices, for intervention, or for a combination of these."*

The very fact that one of the stated objectives of the 'Controllable Dose' concept is to deal with the "grey area" between practices and intervention should have triggered a more specific consideration of how the concept could be used to advantage to accommodate exposures to natural sources more appropriately into the system of protection.

An example of where a pragmatic approach is needed for naturally occurring radioactive material has been given in (i) above, with respect to the proposed 0.3 mSv/a criterion for exemption and clearance. Another example relates to public dose limits and constraints. Some members believe that the approach to public dose limitation proposed in the 'Controllable Dose' paper offers no advance beyond the current system of protection, other than to further encourage the demise of the 1 mSv public dose limit in favour of a rigid single-source "limit" of 0.3 mSv/a. They further feel that this might be appropriate for man-made radionuclide sources but, in the spirit of the 'Controllable Dose' concept, further thought is needed on more imaginative and practicable ways of dealing with the limitation of doses to the public from naturally occurring radioactive materials.

Many members were quick to point out the dangers of creating public perceptions that standards of protection for sources containing natural radionuclides were different than those for man-made radiation sources. Although all members agree that this is a valid concern, some argue that it is one that the 'Controllable Dose' concept has been specifically designed to overcome, in the same way that it has been designed to address the existing public confusion over the large differences between dose limits, action levels and intervention levels. They quote the control of radon as an example of where protection levels for natural sources of radiation are already perceived as being different from those for man-made sources, and is cited in the paper as one of the problems that the 'Controllable Dose' concept seeks to overcome.

iii) Exposures to Radon

Exposure to radon is, of course, just a particular sub-category of exposure to natural radiation sources and should in principle be treated in the same way. However, there has been a tendency to treat it separately - being a gas, radon can readily accumulate in potentially hazardous concentrations in dwellings and workplaces. It has accordingly received special attention by the ICRP and Action Levels unique to radon have been established.

The rationale behind the 'Controllable Dose' concept has, in some of our members' opinion, provided for the successful integration of these special protection criteria for radon into the overall system of protection.

Some members feel that the same rationale should be applied to exposures to natural sources of radiation other than radon, so that appropriate protection criteria for such exposures can be

established as part of an overall, cohesive system of protection rather than being seen as being in conflict with criteria for man-made sources.

The one concern that was raised by members with respect to radon was that the tendency to treat it separately can be taken too far. In justifying a single-source dose limit of 0.3 mSv/a to a member of the public, it is argued that this value is similar to the variation in background radiation excluding radon. Many members regard this argument as illogical, since the exclusion of radon in this instance is seen as a purely arbitrary decision.

Some members agree that natural background variations could have an important role to play in determining appropriate protection criteria within the proposed new system, a possible example being the criteria for remediation/clearance of contaminated land. However, all sources of natural background exposure, including radon, should be taken into account.

iv) Public Dose Limitation

Members generally felt quite strongly that the proposed approach to the management of controllable doses to the public was inconsistent with the overall protection approach outlined earlier in the paper. Having been led to understand that there would be only one overall "limit" at around 30 mSv/a, with a series of investigation levels below this value, members felt that this was in conflict with the statement that:

> *"A fraction of a millisievert would be the most that would ever be allowed from a single source, irrespective of the number of sources".*

Although all agreed that this appeared incoherent, members had differing views on how this situation should be dealt with. While some agreed with the statement but felt that the incoherence has to be addressed, others felt that the above statement was not only effectively a rigid, legally enforceable limit, but that such a limit was being set close to the lower extreme of the controllable dose regime. As mentioned earlier, this was considered to be in an area with considerable uncertainties over the harmful effects of radiation, because of variations in background radiation and biological susceptibility, and in the dose-response relationship itself. In view of this, some members felt that the area below 3 mSv/a was precisely the area in which prescriptive limits should be avoided, especially when, as was the case here, they were by necessity conservatively based because of the assumption that the number of sources was indeterminate.

Concerns were also expressed by some members about the proposal to dispense with the concept of controlling an individual's exposure to all relevant sources (currently expressed as a limit of 1 mSv/a). It was felt that, at the very least, the dose to an individual from all relevant sources needed to be taken into account when deriving single-source restrictions, but this was not the only cause for concern. While they recognized the difficulties in regulating the exposure of individuals purely on the basis of the current 1 mSv/a, they also envisaged difficulties in regulating purely on the basis of single sources.

In many situations, it is not at all clear how one goes about deciding upon what constitutes a single source. For instance, how does one deal with a mining and minerals processing complex occupying a land area of 100 km^2, or a group of adjacent mining operations that have a collective impact on the atmosphere or on a particular water course or aquifer? Similar problems can arise in the medical field where, for instance, a single source could mean a single X-ray unit or a large number of such units at one site.

Depending on how a single source is defined, the number of individuals exposed could, in the same situation, range from a few persons to hundreds of thousands. This can cause major difficulties in the optimization of protection.

Even if the various sources can be unequivocally defined, protection of the public based solely on single-source control in terms of the proposed system requires that conservative allowance be made for the (unknown) combined impact of all relevant sources. There was some concern expressed that this could lead to the imposition of source-related dose restrictions that are over-restrictive and unreasonable. Problems of this nature are already starting to be voiced by the South African mining industry.

Some members feel that in situations involving significant public exposures from multiple sources, such as a group of adjacent mining operations, it may be better for the impact on the public to be assessed on a collective or regional basis. They feel that the acceptability or otherwise of such impact should then be judged according to dose criteria not greater than a few mSv/a (a level of the same order as the current 1 mSv/a public dose limit and at which, in terms of the proposals, "the exposures should not be of great concern from the point of view of an individual's health"). They feel that the exact value for a given situation should, in terms of the 'Controllable Dose' concept, be determined taking practical considerations into account. In any event, an individual dose greater than about 3 mSv/a would not be considered acceptable under most circumstances, on the grounds that the exposed individual is deemed to derive no direct benefit from the operation.

It was also pointed out that there is in any case a tendency for environmental legislation to require different industries to accept collective responsibility for pollution control in a particular region.

RECOMMENDATIONS

Recommendations on the concept Itself

- More consideration needs to be given to the approach to the protection of the public, especially for situations such as those associated with activities involving naturally occurring radionuclides, which do not easily fall into the present categories of 'practices' or 'interventions'. In this regard it is recommended that it may be useful to identify actual situations and to subject them to broad international consideration.
- The following concerns should be addressed:
  - the proposal to continue using a "limit" of 0.3 mSv/a for single sources;
  - the terms "particular source" or "single source" are open to wide variations in interpretation; and
  - the practicality of controlling dose purely on the basis of single-source considerations - there is a need to examine whether multiple-source considerations should also continue to apply.
- The application of the system of protection at doses of up to a few hundreds of microsievert and below warrants more consideration. It may be useful for the actual problems that are being experienced to be identified on an international basis. In the South African context these would include issues involving the clearance or exemption of bulk quantities of wastes and residues from the mining and processing of minerals and ores.
- The proposal to dispense entirely with the use of collective dose should be reviewed - collective dose may continue to have a role to play in the optimization process. Serious consideration should however be given to a generic cut-off level for the optimization of protection.

Recommendations on the Presentation and Application of the Concept

- The use of the term “controllable” should be reviewed to ensure that it does not give rise to confusion or misunderstandings regarding the fundamentals of any proposed new approach.
- Some thought needs to be given, at least on a preliminary basis, to the difficult question of translating the principles of the ‘Controllable Dose’ concept (which are to a large extent based on judgemental factors) into explicit regulatory requirements. Guidance will be especially needed on how to define and quantify the terms “benefit to the individual” and “ease of reducing or preventing the dose” as these are fundamental to determining the significance of a level of controllable dose, and hence the specific control measures to be adopted in practice.
- The move away from the entrenched concept of “limits” is a particular issue that will have to be addressed in terms of public understanding and acceptance - also there is the problem of current limits being seen to be moving arbitrarily up or down in the interests of rationalization or unification.
- Clarification will be needed as to whether the proposed system of protection can be truly complementary to the current system, or whether it will represent a whole new system of protection. If a new system is envisaged, the serious concerns regarding the disruption that this will cause and the way in which the transition will be managed need to be addressed.

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ANNEXE

Highlights of the Topical Session – IRPA 10: Critical Issues and Alternative Approaches to Setting Radiation Protection Criteria

Chair and Keynote: G. Webb
Co-Chair: J. Lecomte

Progress towards new Recommendations from ICRP

This session was started by Dr. Webb, who stated that it was a unique opportunity to contribute to the development of ICRP recommendations at a formative stage. He congratulated Dr. Clark on his bravery in initiating the "controllable dose" debate and the societies and individuals who had put in much hard preparations for this session.

Dr. Clarke set the scene for the discussions. He clarified that the main objectives of the exercise were to examine possibilities for changes in the philosophy and frame work of the existing system, where particular difficulties arose in understanding, clarity and operational implementation. The main endpoint for this was a system that would be simpler and easier to use, and most importantly one that would achieve greater public understanding and support. He reiterated that this was evolution not revolution and in many ways flowed from qualifications introduced in ICRP 60 and developed in subsequent publications. It was also necessary for changes in emphasis to be made to recognize the shift in societal expectations towards a more equity-based ethical system. Dr. Clarke then set out the key features of his proposed new system, highlighting the areas where he had already responded to comments on his original suggestions. Following this introduction, presentations were made by the French, German/Swiss, USA, Nordic, South African, UK, Japanese and Spanish societies on the results of their preliminary consultations. A paper was also presented prepared by the CRPPH of OECD/NEA. Responses from the floor included delegates from Australia and New Zealand, Japan, the Netherlands, Hungary and India, and referred to further position papers that had been developed. Although it was not the intention of the session to reach any consensus, nonetheless some early common themes emerged from the papers and discussions.

- The process and mechanisms for engaging the protection community through IRPA and the societies in the review of new ICRP proposals were universally welcomed and applauded.

- It was necessary first to concentrate on rectifying defects or weaknesses in the present system before introducing more radical changes or even a new system of protection. In making such changes, it would be important to take account of the benefits and the costs of change.

- In several areas of the present system the fundamentals were appropriate, but there is still a lack of clear interpretation as to how they are applied in practice, in a manner that is transparent and acceptable to practitioners, workers, and the public. ICRP could help in this, but it is also a matter for organizations including IRPA, IAEA, and NEA.

- Other stakeholders including professionals, interest groups, and the public, need to be brought into the debate. Professionals were cautioned that they too often assumed knowledge of what concerned and confused the public and other non-specialist groups without checking this assumption. The mechanisms for wider consultation and involvement need to be developed and the role of IRPA and societies in these clarified.

- It will be necessary to integrate protection of the environment, including biota, in the new system, but much work needs to be done before this can be achieved.

- Great care is necessary with language, terminology and concepts, especially in not introducing new definitions unless they are absolutely necessary.

- More thinking and development is needed on the way in which quantities such as collective dose and concepts such as ALARA/ALARP are used in the new system.

- Whatever revisions to the current system are proposed, these should be carefully "road tested" for their application before being firmly adopted. In conclusion, Dr. Webb said that all the presented papers, society position papers and statements would be transmitted by IRPA to ICRP with a summary of the discussions. Dr. Clarke advised that the next stage would be a revised draft from ICRP, taking account of all the comments and feedback received. It was likely that this second draft would not be entitled "controllable dose".