PROGRESS TOWARDS NEW RECOMMENDATIONS FROM THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

Roger H Clarke
Chairman, International Commission on Radiological Protection

ABSTRACT

The carcinogenic risks of exposure to low level ionising radiation used by ICRP have been challenged as being, at the same time, both too high and too low. This paper explains that the epidemiological evidence will always be limited at low doses, so that understanding the cellular mechanisms of carcinogenesis is increasingly important to assess the biological risks. An analysis is then given of the reasons why the challenges to ICRP, especially about the linear non-threshold response model, have arisen. As a result of considering the issues, the Main Commission of ICRP is now consulting on a revised, simpler approach which is based on an individual oriented philosophy and represents a potential shift by the Commission from the past emphasis on societal-oriented criteria.

These proposals have been promulgated through IRPA and an open literature publication was published in the Journal of Radiological Protection in June 1999. On the basis of comments received and the observations presented at the IRPA 10 Conference, the Commission will begin to develop the outline of the next Recommendations. It is now more than 10 years since ICRP distributed, for comment, a draft of what was to become the publication of the 1990 Recommendations. The Commission plans to develop its new Recommendations on a time scale of the next four or five years. In this paper, many of the issues that will need to be addressed in the development of the recommendations will be identified.

These issues will cover biological effects, dosimetric quantities and the establishment of those levels of dose at which different protection requirements will be put into place. Concepts of exclusion and exemption will need to be clarified as well as the meaning of how to achieve what the proposal identifies as ‘As Low as Reasonably Practicable’ (ALARP). Finally, the Commission has decided to develop an environmental radiation protection philosophy that will need to be developed as part of the new Recommendations.

INTRODUCTION

The current recommendations were promulgated in the Annals of the ICRP as *Publication 60* in 1991. They replaced the earlier recommendations, upon which ICRP had been building since they first appeared in *Publication 26* in 1977. Those Recommendations presented a ‘System of Dose Limitation’ which was primarily designed for normal operations. Over the years ICRP had extended its advice away from the central core of dose limitation to deal with other exposure situations. These include:

- **radon**, for which a philosophy was developed that did not include dose limits;
- **criteria for solid waste disposal**, where exposures are not certain to occur and events are probabilistic, so that again dose limits are not applicable; and
- **principles for protection of the public in emergencies**, where again dose limits do not apply.

In its 1990 Recommendations the Commission tried to draw together all of these different situations in a ‘System of Radiological Protection’.

Some activities increase the overall exposure to radiation by introducing new sources, pathways and individuals, or by modifying the network from existing sources to man. These activities which add radiation exposures or risks are called "PRACTICES". Other human activities can decrease the overall exposure by removing the source, modifying the pathways or reducing the number of exposed individuals. These activities which subtract radiation exposures are called "INTERVENTION". Controls applied at the source are usually the most effective and least disruptive.

For Practices, the system of protection recommended by the Commission is based on the following general principles:

(a) Practices involving exposure to radiation should produce sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes (justification)

(b) For any source, individual doses, the number of people exposed and the likelihood of being exposed, should be as low as reasonably achievable and constrained by restrictions on the doses to individuals (dose constraints), or risks to individuals (risk constraints) from potential exposures (optimisation)

(c) Individual exposure from all sources susceptible to control are subject to dose limits or some control of risk from potential exposures (limitation)

These principles mean that when they are implemented for practices, it is necessary to consider not only normal operation but also the potential for exposures from accidents. Once the practice is justified - and radiological protection considerations are only one aspect of decision-making over the introduction of a new practice - the doses and risks have to be optimised within the dose or risk limits specified for individuals. However, optimisation is a source-related process while limits apply to the individual to ensure protection from all sources under control.

The principles of justification and optimisation aim at doing more good than harm and at maximising the margin of good over harm for Society as a whole. They therefore satisfy the **utilitarian principle of ethics**, whereby actions are judged by their overall consequences, usually by comparing in monetary terms the relevant benefits (e.g. statistical estimates of lives saved) obtained by a particular protective measure with the net cost of introducing that measure.

The application of the justification and optimization principles to practices may, however, introduce individual inequities, which may be important. Inequities are caused by the spatial distribution of prolonged exposures, which may involve people who are not direct beneficiaries of the practice. They can also be attributed to the long-term temporal distribution of exposure, which may affect future generations. It should be noted, however, that inequity between different generations is a more elusive concept than inequity between different individuals at a given time. In order to limit these inequities and to allow for exposures to multiple sources, stringent individual dose restrictions are applied to the exposures expected to be delivered by individual sources. The exposure restrictions to sources are termed *dose constraints*; the exposure restrictions to practices are termed *dose limits.*

The Commission has therefore introduced the concept of a constraint to dose or risk. A constraint is an individual-related criterion, but applied to a single source in order to ensure that dose or risk limits are not exceeded. A dose constraint would therefore be set at a fraction of the dose limit, as a boundary on the optimisation of that source. Thus concern for the protection of the individual was being strengthened. The Commission now recommends a maximum constraint of 0.3 mSv in a year.

In some situations, the sources, pathways, and exposed individuals are all in place when a decision on control has to be taken. In this case, the reduction in dose is achieved by intervention. An important group of such situations is the exposure from natural sources of radiation. Accidents and emergencies will have been considered as sources of potential exposure when assessing a practice but, if they occur, they may call for intervention.

Intervention cannot usually be applied at the source and has to apply to the environment or people. Countermeasures forming the intervention have disadvantages, so they must be justified as doing more good than harm. The system of radiological protection recommended by the Commission for Intervention is thus based on the following general principles:

(a) Any intervention must do more good than harm so the reduction in radiation detriment must exceed the harm and social cost of the intervention.

(b) The scale and duration of the intervention should be optimised such that the net benefit of the reduction in dose, i.e. the benefit of the reduction in radiation detriment less the detriment associated with the intervention, should be maximised.

Principles (a) and (b) will lead to intervention levels that are appropriate for the circumstances. However, there will be some level of projected dose above which, because of serious deterministic effects, intervention will almost always be justified.

The intervention situation differs from that of the practice in that action is being taken to reduce the level of exposure as much as reasonable, whereas with the practice the objective is to restrict added exposures and the risk of being exposed. The two situations normally quoted for intervention are radon in buildings and countermeasures for the public after a nuclear accident. In both cases, protection measures taken are designed to lower the dose and hence dose limits do not apply. The question is by how much are the doses and therefore the risks to be reduced? Since there is some harm to the affected individuals from the disruption and risk of executing a countermeasure, the philosophy is to maximise the difference between the risk averted by the reduction of dose and the risk added by the countermeasure. In this scenario, there is no equivalent to the unacceptable level of risk although there must be a 'limit' to risk when the effects on the individual from the radiation are so severe, for example serious deterministic effects, that intervention is bound to be justified.

For both Practices and Interventions, the Recommendations from ICRP in the last ten years have been made in terms of controlling the maximum risk to the individual. For normal operations, waste disposal and intervention, standards are set based on individual risks that are in a range which is between the 'unacceptable' (above 1 in 1,000 per year) and the 'trivial' (below 1 in 1,000,000 per year). There has been a corresponding reduction in the emphasis on collective dose and cost-benefit analysis. Overall this reflects a shift from utilitarian values to an equity-based policy, which starts with the premise that all individuals have unconditional rights to certain levels of protection. This seems to be more in line with the changing values of Society to have more concern about individual welfare.

THE CURRENT PROBLEM

In recent years questions have been raised about the Commission's application of its risk factors at low doses. ICRP has attempted to analyse why the questions have arisen and, as a result, some proposals are now made for a different, less complex, approach to protection. The Commission is considering a consolidation or recapitulation of its 1990 Recommendations and wishes the ideas to be widely discussed as part of the process leading to a restatement of its protection policy.

The challenges to the so-called linear non-threshold hypothesis have arisen, it seems, mainly because of the problems of contaminated land. As discussed above, it arises as a result of accidental releases, as from Chernobyl, and from manmade activities including atmospheric testing of nuclear weapons. Contamination is also an historic liability from, for example, luminising plants using radium, or from excessive effluent discharges.

A particular issue at present is the decommissioning of nuclear facilities, old reactors and weapons fabrication facilities. These liabilities require the expenditure of considerable amounts of money and some people think that too much money is being, and will be, spent to achieve low levels of residual contamination. If contaminated land is not cleaned up there is public concern and in some countries there will be litigation, charging that the environmental risk is too great. These concerns have led to an increased pressure from some individuals to propose a threshold in the dose-response relationship in order to reduce the expenditure. The issue is primarily in relation to public not occupational exposure.

Another aspect of concern is the use of Collective Dose to add up infinitesimally small doses to essentially infinite populations over essentially geological timescales and to cost it so that it is argued that it is worth committing huge resources today to protect the future. ICRP has already begun to tackle this by recommending, in *Publication 77*, the dis-aggregation of the single value of a collective dose into ranges of individual dose and the period of time when it is delivered. Further it cautions against the use of estimates of doses and health effects in the far future. It should also be noted that the criteria developed for prolonged exposures, outlined above, find little application for collective concepts.

DIFFICULTIES WITH A THRESHOLD

A simple proportional relationship has important practical implications since it 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.

These practical implications are of overwhelming importance in radiological protection because of the complexity of the dose distributions in both space and time and because of the ubiquitous presence of natural sources of radiation. Very substantial difficulties would be introduced if threshold relationships were widely relevant in radiological protection. Threshold relationships exist for deterministic effects, but the levels of dose of concern in protection are generally well below these thresholds. When this is not so, as in radiotherapy, a single source of dose is predominant so that interaction between different sources can be neglected. One example of the complexities that would be introduced by a widely applicable threshold relationship would be the interaction between occupational exposure and non-occupational exposure to natural sources, and diagnostic medical exposure of individual workers. In order to control the risk it would be necessary to record all doses people received and with a threshold, protection by design is almost impossible.

It is true that, 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.

There are uncertainties due to both biology and epidemiology in the risk estimates from exposure, although it must be remembered that the exposures are always increments on the existing natural background radiation of a few mSv per year. Because of the continuing lack of definitive scientific evidence, a new approach to protection could be considered.

CONFUSION WITH THE PRESENT SYSTEM

ICRP has made clear that the present system of protection distinguishes between practices, which add doses and risks, and interventions, which reduce doses and risks. The dose limits apply to the sum of doses from a restricted set of sources or circumstances and, additionally, are often misunderstood, since a limit is sometimes taken to mean the boundary between safe and unsafe. For public exposure in particular, there is confusion about the application of the 1 mSv annual dose limit when the Action Level for radon in homes is to be set between 3 and 10 mSv in a year. Then, in the event of an accident, perhaps when people especially expect to be protected, the dose limit does not apply and intervention is not taken until doses are liable to be in the range of 5 to 50 mSv.

ICRP recommendations, in the context of the use of radionuclides, have been for the control of protection from single sources by optimisation within the individual maximum dose constraint of 0.3 mSv per year. In the case of accidents, intervention levels have been suggested for taking action to reduce exposures, but at what level of dose can normal living be resumed? More than 1 mSv per year surely, and if a new population moves from outside into the area and begins a new activity, is it a practice to which the 1 mSv dose limit applies? Thus, at what point after an accident do the principles of protection for practices apply, if at all?

These are situations that do not easily fall into the current definitions of practice or intervention; however, current radiological protection philosophy has been applied in *Publication 82* to develop a consistent framework for protection in the case of prolonged exposures.

The difficulties outlined and the uncertainties in estimating risks from low-level radiation exposure have led ICRP to consider whether there might be some alternative way to deal with the control of dose. In formulating the proposals, an attempt has been made to try to simplify the system of protection.

THE FUTURE – HOW SHOULD EXPOSURES BE CONTROLLED?

In protecting individuals from the harmful effects of ionising radiation, it is the control of radiation doses that is important, no matter what the source. Thus, consideration should be given to the dose or the sum of the doses to an individual from a particular source that can reasonably be controlled by whatever means.

Such doses could be received at work, in medical practice and in the environment from the use of artificial sources of radionuclides, or could arise from elevated levels of natural radiation and radionuclides, including radon. The term covers doses that are being received, for example, from radon, and doses that are to be received in the future, from the introduction of new sources or following an actual or potential accident. It does not apply to exposures that are not amenable to control, such as cosmic radiation at ground level, but would apply to high terrestrial levels of natural exposure.

In the past ICRP has adopted a societal ethical policy using a utility-based criterion, in which the aggregated collective dose is used, principally in cost-benefit analysis, to determine the optimum spend on the control of a source. What is now being developed is a more individual based ethical philosophy, an equity-based criterion, which was foreshadowed by the introduction of the concept of a constraint on the optimisation of a source and the Commission's recommendations on dis-aggregation regarding Collective Dose. The proposed protection philosophy is based on the protection of the individual. If the individual is sufficiently protected from a single source, then that is a sufficient criterion for the control of the source. The principle is 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.

The significance of a level of dose depends on its magnitude, the benefit to that individual and the ease of reducing or preventing the dose. There will, of course, be some level of dose where control will be mandatory.

This will clearly be for the avoidance of deterministic effects in accident situations or for the protection of healthy tissues in high dose medical procedures.

A PRACTICAL SOLUTION

A suggested way forward may be to work toward a single scale of individual dose. A possible single scale with descriptors of the importance of the exposure is shown in Figure 1. Under most circumstances, the maximum value would be around some tens of mSv in a year. In fact the present system of protection recommends taking action at some tens of millisieverts, whether it is occupational exposure in a practice or public exposure in an intervention. Doses significantly above this level only occur in uncontrolled accident situations or in life-saving medical procedures and require urgent action. It may be that rather than referring to this value as a limit, the term Action Level should be used. In fact, that is what it would be - if doses (actual or projected) that can be controlled are above this level action should be taken. This may have an advantage that Action Levels are understood, whereas a "limit", as has been said, can be and often is misunderstood. Above this Action Level it may be the total dose that is of concern, although one particular component may be dominant, for example an occupational exposure, and that is the component to be controlled. On the other hand in an area of elevated external natural background, it is the total dose that has to be considered.

INDIVIDUAL DOSE SCALE

	Dose (mSv)
SERIOUS	30 - 300
HIGH	3 - 30
MODERATE	0.3 - 3
LOW	0.03 - 0.3
TRIVIAL	< 0.03

Figure 1. A proposed individual scale of effective dose and a description of the importance of the dose.

The management of individual 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, simple medical procedure doses, exposures from domestic radon or from other elevated levels of natural radionuclides, and those after an accident. The need for distinguishing between practices and interventions may no longer be required. This Investigation Level of a total dose of around a few millisieverts per year would prompt an investigation to see if any one source was dominant and if anything simple could be done to reduce the exposure.

Within this scheme, exposures of a fraction of a millisievert would be the most that would ever be allowed to a member of the public from a single source, irrespective of the number of sources - effluents from a hospital, from a power plant, a diagnostic x-ray, a smoke detector, etc. These sources would be treated independently because the chance of one individual being exposed to all sources is very small and actual exposures from several sources would be unlikely to amount to more than a fraction of a millisievert. The term Constraint could still be retained and the principle of optimisation applies for each source.

At the lowest level, doses of a few tens of microsieverts would be considered to be so low as to be exempted from regulatory action. There would be no need to involve any control system below these levels. The resulting regulatory system might be as shown in Table 1.

	QUANTITY	EFFECTIVE DOSE(mSv)
Action level	EXISTING DOSE	~30
Investigation level	EXISTING DOSE	~3
Constraint on single source	ADDITIONAL DOSE	<0.3
Exemption level	ADDITIONAL DOSE	<~0.03

Table 1. A potential Regulatory System for the control of individual doses.

THE CONSEQUENCES

The proposals presented here put the primary emphasis for the system of protection on the individual, by adequately restricting the sources that may reasonably be controlled. The Commission's principles of justification and optimisation would next need to be reconsidered. 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 elevating the principle of justification to the responsibility of governments and their regulatory agencies. This would remove justification from the radiological protection recommendations, which would then start with consideration of an already justified practice.

The existing principle of optimisation would be recast and clearly guidance would need to be developed on its application. This would be require the replacement of "as low as reasonably achievable", which has been too associated with cost-benefit analysis and the use of collective dose, with another descriptor when individual dose is the determining criterion. If at some time in the future it became possible that some individuals might be liable to receive, in due course and over a prolonged period of time, a significant accumulation of doses from many sources, local, regional and global, then a further restriction on sources may be necessary. There would, however, be likely to be a considerable time period available to effect change.

The principles of protection might then become

- control the dose to the representative member of the most highly exposed group, and
- ensure that resulting dose is "as low as reasonably practicable"

These may be known as 'Control' and 'ALARP'. There would be considerable scope for a simplification of the system of protection and remove confusion by not distinguishing between Practices and Interventions. Additionally, it may be that there is no longer a need to differentiate between Occupational, Public and Medical exposures. The same guidance is equally applicable for protection of each category. Any particular concerns about the protection of the unborn child would also be covered, by the constraint of a fraction of a millisievert and investigation level of a few millisieverts. There would be no need for the existing 1 mSv dose limit for the public.

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There would be no use made of collective dose as presently defined unrestricted in space and time, 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. There will, however, be some sub-sets of collective dose that do have utility. The most obvious of these is in occupational exposure related to the execution of a particular task and it may be better to define a new term, such as **Workforce Dose** to preserve the value but avoiding the infinite connotations of the Collective word. It may also be that the size of the population given the highest levels of dose from a controlled source would be a determinant in deciding what is reasonably practicable. A term would need to be found for this quantity, such as **Local Dose,** and might include the number of people receiving non-trivial doses, i.e. greater than some tens of microsieverts from that single source. In cases where the existing dose is high, say, some few millisieverts a year and perhaps due to terrestrial sources or previous unregulated practices, then again the size of the affected population is a major determinant of whether intervention is practicable.

This more straightforward single scale system of protection is consistent with the present system based on acceptable risks, but importantly may be explained to individuals more understandably as multiples or fractions of the natural background. In essence, with the present system, action is taken if exposures are more than about ten times the natural background, whether it is at work in a practice or intervention for the public. Equally, individual sources are controlled at about one tenth of natural background and exemption is set at about one hundredth of natural background.

Finally, it is probably no longer sufficient for ICRP to state its belief that 'the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk'. An advantage of the proposed dose system is that it may facilitate the development of an environmental protection strategy for radiation based on multiples of background radiation and this may also be more compatible with those for other environmental agents.

CONCLUSIONS ON PROTECTION PHILOSOPHY

Radiation has been used for the last one hundred years during which time there has essentially always been advice on protection from the harmful effects while not wishing to restrict the benefits. For the first sixty years, until the middle of the twentieth century, protection was concerned with keeping individual doses below the thresholds for deterministic effects. Low levels of radiation were deemed beneficial and radioactive consumer products abounded.

Throughout the next period of protection, from the 1960s to 1990, the Commission was dealing with stochastic risks where the probability of harm was proportional to dose. The question had become one of acceptability of risk, since there was no threshold below which there was zero risk. This acceptability was determined by what was 'As Low As Reasonably Achievable' and the methods used were Cost-benefit Analysis using Collective Dose. In essence the principle was to protect society and the individual will be adequately protected.

Recommendations from ICRP in the last ten years, however, have been made in terms of controlling the maximum stochastic risk to the individual. There has been a corresponding reduction in the emphasis on collective dose and cost-benefit analysis. Overall this reflects a shift from utilitarian, or societal-based values, to an equity, or individual-based policy, which is in line with changing values in Society which appear to show more concern about the welfare of the individual.

Currently there are challenges to the use of the so-called linear non-threshold model for predicting risks at low doses. This seems to be a reflection of concern about the expense of cleaning up contaminated sites and the use of collective dose unrestricted in space and time.

For the future, ICRP is considering an individual-based philosophy using the concept of controllability of sources. This will protect against both stochastic and deterministic effects, and may provide a simpler single scale of protection levels. This could have advantages by being similar to the methods used to control other non-radioactive pollutants, thus offering the potential for an integrated policy. It may also allow the development of a straightforward philosophy for protection of the environment and species other than humans from radiation damage.