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

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Abstract. The carcinogenic risks of exposure to low-level ionising radiation used by the 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 the ICRP, especially about the linear non-threshold response model, have arisen. As a result of considering the issues, the Main Commission of the ICRP is now proposing a revised, simpler, approach based on the concept of what is being called 'controllable dose'. This is an individual-based philosophy and represents a shift in emphasis by the Commission from societal-oriented criteria using Collective Dose. Finally the paper speculates on the consequences for radiological protection of such a change in policy. The Commission wishes its ideas to be discussed as part of its reconsideration of its recommendations.

1. Introduction

It is now ten years since the ICRP promulgated a draft version of what was to become the 1990 recommendations. That consultation process helped the Commission to clarify its aims and the expression of its philosophy. Since the issue of Publication 60 [1], the Commission has further elaborated its policy on a number of issues such as, control of exposure to radon-222, criteria for intervention after an accident, the management of occupational exposure, and its policy for the disposal of radioactive wastes.

However, in recent years questions have been raised about the Commission's application of its risk factors at low doses. This article discusses the current ICRP position and attempts to analyse why the questions have arisen. Some proposals are then 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 in this paper to be widely discussed as part of the process leading to a restatement of its protection policy.

2. Carcinogenic risks of low-level radiation exposure

2.1. Epidemiological evidence

Some of the most critical judgements in radiological protection have been associated with estimating the risk of excess cancer following low-dose irradiation of human populations [1–4]. The most difficult problem surrounding these judgements is that epidemiological approaches such as those used with the Japanese A-bomb survivors have only the power to identify excess risk down to low-LET radiation doses of around 50–100 mGy [5]. However, some analyses of the Japanese survivor data are claimed to show no excess below 200–300 mGy, and certainly some other cohorts appear to demonstrate risks only at higher doses than the data from the Japanese studies.

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Below doses of a few hundred mGy, statistical power is progressively lost and direct estimates of cancer risk in a population of all ages becomes increasingly difficult and then impossible. Lower background cancer rates in children allow for estimation of *in utero* radiation risks down to about 10 mGy [3, 6], although these analyses are being challenged. But the problems of estimating the risk at occupational and environmental exposure levels of radiation remain.

Experimental limitations create essentially the same statistical problem in studies of animal carcinogenesis. However, in the last 10 years or so advances in biology, often based upon molecular genetics, have increasingly complemented the conclusions from epidemiology [2, 4].

2.2. Mechanisms of carcinogenesis

There is compelling evidence that cellular DNA present in the chromosomes of the cell nucleus acts as the principal target for spontaneously arising and carcinogen-induced tumours in humans and experimental animals [3, 4]. The DNA damage relevant to initial tumour development takes the form of gene and chromosome mutations that often appear to be specific to different tumour types.

There is abundant evidence that the capacity of irradiated cells to repair DNA damage acts to reduce mutational and tumorigenic risk. An argument used by some is that the low abundance of DNA damage at low doses allows complete and error-free cellular repair. According to these proposals it is only at high doses where repair capacity is saturated that tumorigenic risk becomes apparent. The proponents of this hypothesis support their argument with data showing that the abundance of spontaneously arising DNA damage arising in cells is very much greater than that induced by a low dose of ionising radiation, say 200 mGy—how can there be excess cancer risk at these low doses?

A large body of data reveals the critical flaw in this argument [4]. These data show clearly that spontaneously arising DNA damage is chemically simple, principally in single DNA strands and is readily repaired by the cell with a very low frequency of error, so that mutation rates are low. In contrast DNA damage produced by ionisation clusters within single radiation tracks is usually not chemically simple and can take the form of complex breaks in both strands of the DNA molecule. This complex damage is very difficult to repair correctly and as a consequence mutation rates are very much higher than that associated with spontaneous DNA damage. In accordance with these observations, dose-response relationships for gene and chromosomal mutations have been shown to be approximately linear down to doses of around 25 mGy, which is the statistical limit of their power. At present, the evidence available supports the view that ionising radiation acts most strongly as the early initiating phase of tumour development by inducing specific gene loss in stem cells [7].

Stated simply, although there are good reasons to believe that DNA damage repair in cells does act to substantially reduce the risk of radiation tumorigenesis, current knowledge does not support the concept that at low doses these repair functions can abolish such risk. Associated arguments for a dose threshold dependent upon the postulate that low-dose irradiation induces additional DNA repair capacity lack adequate supporting data and also fail to take account of the complex DNA damage problem noted above [8].

In the absence of directly informative quantitative data on radiation tumorigenesis, the shape of the low-dose response has to be judged on indirect data on the cellular mechanisms involved in the whole of this complex process.

In essence, this judgement has and will continue to be made on the basis of ‘weight of evidence’ since there are no prospects that the existence of a low-dose threshold for tumour induction could be proved or disproved conclusively. 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. Indeed data from experimental animals for certain tumour types and radiation quality do provide some evidence of this; one possible explanation of these data is that in some situations it is necessary to produce a degree of normal tissue damage before tumour development will proceed.

It is important to stress, however, 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.

The same general considerations apply to a controversy of more recent origin than that of threshold doses, namely the cellular phenomenon of radiation-induced persistent genomic instability [9]. It has been claimed by some [10] that the finding of this phenomenon poses a challenge to accepted concepts in radiological protection, and that risks may be higher than currently judged. The phenomenon has yet to be associated with tumour risk or other possible health effects [11]. Also, even if it were to be established, there would be no obvious implications for the direct epidemiological-based central estimates of cancer risk on which risk projections are founded. Nevertheless, the development of this new area of speculation on possible underestimation of low-dose risk provides an interesting counterpoint to the longer-standing debate on dose thresholds and the entirely opposite claims of its proponents.

In conclusion, 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 [2, 4].

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: do more good than harm.
- Optimisation: maximise the margin of good over harm.
- Limitation: Individual risk should not be unacceptable.

3. What is the problem?

It is useful to ask why it is that challenges to the so-called linear non-threshold hypothesis have arisen.

Contaminated land is an issue of considerable interest in many countries. It arises as a result of accidental releases, as from Chernobyl, and from man-made 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 disaggregation 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 [12].

4. 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.

As has been said above, there is uncertainty in risk estimates due to both biology and epidemiology, 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.

5. Confusion

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 [1, 12]. 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 [12]. In the case of accidents, intervention levels have been suggested for taking action to reduce exposures, but there is no international guidance on the withdrawal of intervention actions. 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, 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? Along these lines, is building a house in an area of high natural background radiation to which people might move from areas of lower background, a practice to which the 1 mSv limit is applied? Strict application of the definition of a practice given in ICRP Publication 60 might suggest that this is so.

These are situations that do not easily fall into the current definitions of practice or intervention; radiological protection philosophy might usefully be re-examined in order to develop an alternative logically consistent framework for protection to that used at present. The following thoughts are for discussion and are a first attempt to do this by bringing the three categories of exposure, occupational, medical and public, within an overall framework that encompasses the present system of protection for practices and interventions. These represent a scheme that may be complementary to, rather than a fundamental change in, the Commission's system of protection and may be of use in its application.

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.

6. A possible way forward

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, a start may be made with a definition:

> A *Controllable Dose* is 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, for example 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 emphasized societal criteria, using collective dose summed over all populations and all times, 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 philosophy, which was foreshadowed by the introduction of the concept of a constraint on the optimisation of a source and the Commission's recommendations on disaggregation regarding Collective Dose [12].

7. The principle

The protection philosophy for controllable dose is based on 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

> 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.

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. 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.

Doses of some hundreds of millisieverts up to several sieverts will cause deterministic effects of various types depending upon whether the exposure is acute or chronic. Apart from in radiotherapy, such doses may be encountered in interventional radiology, where there is a life-threatening situation. In other circumstances, such exposures will be entirely unacceptable to the individual, unless taken for life-saving rescue in an emergency. These situations are considered to be outside the scope of the proposed scheme of controllable doses set out here.

8. Controllable dose

For those exposures that are to be controlled, the philosophy is essentially set out here with a regime of controllable doses showing their different significance in terms of individual fatal cancer risk. In addition, the current criteria for controlling doses in normal, accident or medical situations are presented.

Thus, the highest dose that will normally be tolerated before control is definitely instituted is in the range of a few tens of millisieverts although this may be tolerated in successive years. This covers, *inter alia*:

- The permanent relocation of people following an accident is recommended to avert a lifetime dose of 1 Sv, which corresponds to some tens of mSv in the first year.
- The occupational dose limit of 20 mSv in a year.
- The upper (justified) action level for radon in homes (10 mSv per year).
- A CT scan (around 30–50 mSv).
- The lower level of averted dose above which evacuation is recommended after an accident (50 mSv).

The level of individual risk represented by some tens of mSv would be of the order of 1 in 1000 or 10^{-3}. While these levels of dose to the individual are not so high as to be completely unacceptable, they are levels at which questions should be asked as to whether the dose and associated fatal risk can be avoided by some sort of action. That action may be disruptive by intervening in lifestyle, or, as in the case of a CT scan, be simply to be sure

that the required information cannot be obtained by another means, for example, magnetic resonance imaging.

Controllable doses should not generally exceed this level and actual or potential doses approaching this level would only be allowed if the individual receives a benefit or the doses cannot be reduced or prevented without significant disruption to lifestyle.

At levels of controllable dose of the order of a few millisieverts, the exposures should not be of great concern from the point of view of an individual's health. Natural background radiation is about 2–3 mSv in a year, and even if radon exposures are excluded, the figure is 1–2 mSv. Typical exposures in the range would be:

- The lower level of optimised range for radon intervention (3 mSv).
- The lower level for simple countermeasures (sheltering, KI) in an accident (5 mSv).
- The existing dose limit for members of the pubic (1 mSv).
- Simple diagnostic x-ray examinations (few mSv).

Steps may be taken to reduce these exposures, or to prevent them, particularly if the individual receives no benefit. Thus from a controllable dose of a few millisieverts upwards it becomes increasingly desirable to reduce or prevent the dose depending both on the practicability of doing so and whether the individual is deriving any tangible benefit from the exposure, for example annual occupational exposures or unnecessary doses from medical examinations. The associated levels of fatal risk would be 10^{-4}, 1 in 10 000.

In essence, this is a dose at which there is a question mark. If the medical examination is going to give a dose of a few mSv, again the question of whether an alternative procedure can give the required information should be asked, even though it can be argued that there is benefit to the patient. Similarly if a worker were receiving more than a few mSv, management would probably wish to ensure that the doses were as low as compatible with the job being undertaken. For the public, again action would be contemplated.

Doses that are below the millisievert level are also relevant in the control of exposures. In connection with uses of radiation sources, the Commission has set the maximum dose from a single source to a member of the public at 0.3 mSv a year [12]. The associated level of fatal cancer risk is about 10^{-5} per year. This level of dose is about 10% of total natural background dose and is also of the same order as to variation in background radiation (excluding the radon contribution) over much of the world. This level of imposed or involuntary risk is about the most that has been judged as being tolerated by members of the public.

In comparison, a level of risk of death of 10^{-6} per year is commonly regarded as trivial and the corresponding annual dose of about 10–20 μSv has been used to set exemption criteria for the Inter-Agency or European Basic Safety Standards [13, 14]. At this level of dose there should be no need to consider protection of the individual.

The dose levels discussed above are set out in figure 1, together with the doses that arise from the application of the present system of protection in a wide range of situations. There is, quite deliberately, no distinction between single doses and those that may be received repeatedly. This may be simpler for people to understand. Also, it is controversial to include medical exposures, but perhaps it may help to give the public a broader perspective on doses and risks if all the situations that lead to a given numerical value are put onto a single scale.

9. A practical solution

A suggested way forward may be to work toward a single maximum level of controllable dose. The value would be around 20–30 mSv in a year. 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. In fact, that is what it would be—if controllable doses (actual or projected) 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.

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,

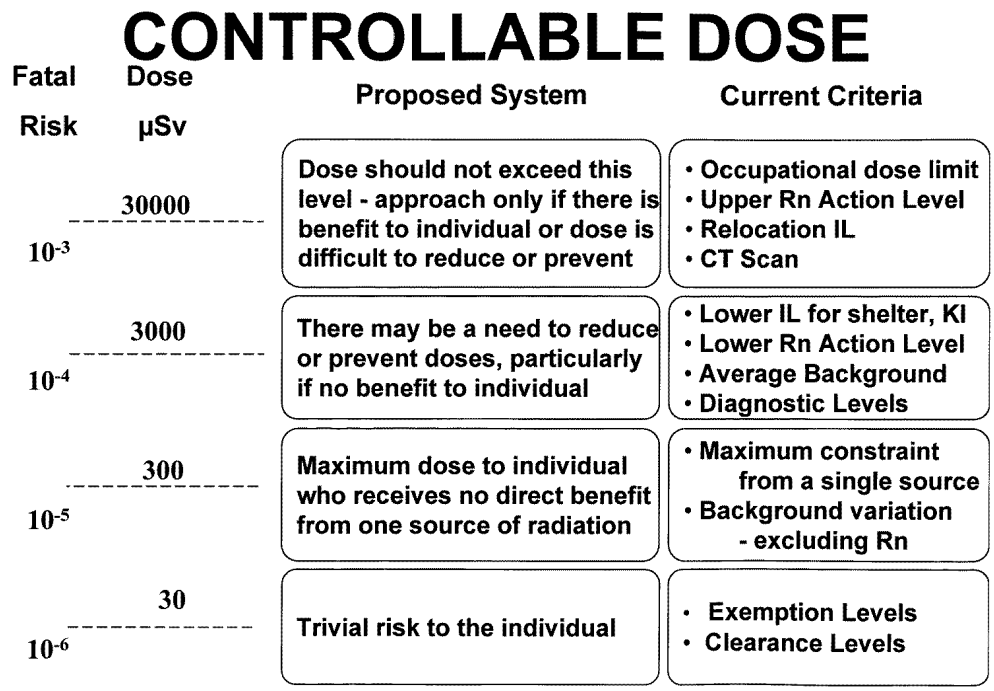

Figure 1.

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 around few millisieverts per year would prompt an investigation to see 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 beneath regulatory concern. There would be no need to involve any system of protection below these levels.

10. 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 dropping the principle of justification from the ICRP system.

The existing principle of optimisation would be recast and clearly guidance would need to be developed on its application. This would require the replacement of ‘as low as reasonably achievable’, which has been associated with cost–benefit analysis and the use of Collective Dose, with another descriptor when individual

dose is the determining criterion. It may be that the number of people affected by the highest levels of dose would be a determinant in deciding what is practicable.

The principles of protection might then become:

- Control the dose to the representative member of the most highly exposed group.
- Ensure that the 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.

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 controllable dose system is that it may facilitate the development of an environmental protection strategy for radiation protection that is more compatible with those for other environmental agents.

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.

Finally, there would be no use made of Collective Dose as currently defined, 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.

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.

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 which case, perhaps there is no need to destroy the credibility of the profession in arguments for or against a threshold.

ICRP would welcome a wide discussion on the concepts of controllable dose and the new proposals for a simplification of protection philosophy that could lead to a restatement of its recommendations.

Résumé

On a contesté l'évaluation des risques carcinogéniques de l'exposition à de bas niveaux de rayonnement ionisant, employée par la CIPR; on la trouvait, soit trop élevée, soit trop faible. Dans cet article, on explique que l'évidence épidémiologique restera toujours restreinte, dans le cas des doses faibles; il en résulte que la compréhension des mécanismes cellulaires de la carcinogenèse est de plus en plus importante pour établir les risques biologiques. On analyse alors les raisons pour lesquelles il est apparu une récusation de la CIPR, en particulier en ce qui concerne le modèle de réponse linéaire sans seuil. Afln de sortir de cette situation, la commission principale de la CIPR propose maintenant un mode d'approche révisé, plus simple, fondé sur le concept de ce que l'on peut appeler la «dose contrôlable». Il s'agit d'une philosophie fondée sur l'individu; elle représente un déplacement d'accentuation par la commission, en partant des critères à orientation «sociétable» utilisant la dose collective. L'article s'achève par des spéculations quant aux conséquences d'un tel changement politique, en ce qui concerne la protection radiologique. La commission souhaite que ses idées soient discutées dans le cadre de la révision de ses recommandations.

Zusammenfassung

Die karzinogenen Risiken der Belastung durch von der ICRP eingesetzte schwachaktiven ionisierende Strahlung wurden in Zweifel gezogen, da sie sowohl zu hoch als auch zu niedrig seien. Diese Studie erklärt, daß die epidemiologischen Beweise bei niedrigen Dosen immer eingeschränkt sein werden, so daß ein Verständnis der zellulären Mechanismen der Karzinogenese immer wichtiger wird, um biologische Risiken abschätzen zu können. Es folgt dann eine Analyse der Gründe warum Zweifel an der ICRP, insbesondere am linearen Ansprechmodell ohne Schwellen, aufgekommen sind. Als Ergebnis der Überlegungen zu diesen Fragen schlägt die Hauptkommission des ICRP nun eine überarbeitete, einfachere Methode vor, basierend auf dem Konzept der sogenannten 'kontrollierbaren Dosis'. Dies ist eine Personen-bezogene Philosophie, die einen Verschiebung

der Gewichtung durch die Kommission von gesellschaftlich orientierten Kriterien unter Verwendung einer kollektiven Dosis widerspiegelt. Schließlich spekuliert die Studie über die Konsequenzen einer derartigen Veränderung der Politik für den Strahlenschutz. Die Kommission möchte, daß ihre Ideen als Teil der Überprüfung ihrer Empfehlungen diskutiert werden.

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