



2003 Recommendations of the European Commission on Radiation Risk (ECRR) on The Health Effects of Ionising Radiation Exposure at Low Doses and Low Dose Rates for Radiation Protection Purposes: Regulators' Edition

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The committee dedicates this volume to the memory of Alice Mary Stewart, the first scientist to establish the health effects of exposure to low dose radiation. Professor Stewart agreed to be the first Chair of the European Committee on Radiation Risk. Sadly, she did not live to see this first report completed.

This first report of the European Committee on Radiation Risk is intended for regulators and those who have to make decisions about the health effects of radioactive releases. It presents a rational model for calculating the health risks of exposure to ionising radiation. Unlike the existing framework of modelling radiation risk, the ECRR model uses evidence from the most recent research, from new discoveries in radiation biology and from human epidemiology to create a system of calculation which gives results which are in agreement both with the mechanism of radiation action at the level of the living cell and observation of disease in exposed population.

There is increasing concern over the

dissonance between the modelling of health outcomes of radioactive releases to the environment and the observations. In this volume the committee explains how the present risk model came to be universally used and points out its shortcomings. In addition the committee addresses the ethical basis of releasing radioactive materials to the environment.

The volume is essential reading for anyone involved in legislation in this area and should also be of interest to members of the public who need to estimate the effects of nuclear discharges.

Price £UK 45 (euro 75)

(Concession price £UK 15 (euro 25))

The committee is anxious to make this volume widely available and therefore has decided to set aside copies to be sold at a concession price for those individuals, student, etc. who may find the full price beyond their means.

Purposes. Regulators' Edition.

Executive Summary

This report outlines the committee's findings regarding the effects on human health of exposure to ionising radiation and presents a new model for assessing these risks. It is intended for decision-makers and others who are interested in this area and aims to provide a concise description of the model developed by the committee and the evidence on which it depends. The development of the model begins with an analysis of the present risk model of the International Commission on Radiological Protection (ICRP) which is the basis of and dominates all present radiation risk legislation. The committee regards this ICRP model as essentially flawed as regards its application to exposure to internal radioisotopes but for pragmatic reasons to do with the existence of historical exposure data has agreed to adjust for the errors in the ICRP model by defining isotope and exposure specific weighting factors for internal exposures so that the calculation of effective dose (in Sieverts) remains. Thus, with the new system, the overall risk factors for fatal cancer published by ICRP and other risk agencies may be used largely unchanged and legislation based upon these may also be used unchanged. It is the calculation of the dose which is altered by the committee's model.

1. The European Committee on Radiation Risk arose out of criticisms of the risk models of the ICRP which were explicitly identified at the European Parliament STOA workshop in February 1998; subsequently it was agreed

that an alternative view should be sought regarding the health effects of low level radiation. The committee consists of scientists and risk specialists from within Europe but takes evidence and advice from scientists and experts based in other countries.

2. The report begins by identifying the existence of a dissonance between the risk models of the ICRP and epidemiological evidence of increased risk of illness, particularly cancer and leukaemia, in populations exposed to internal radioactive isotopes from anthropogenic sources. The committee addresses the basis in scientific philosophy of the ICRP risk model as applied to such risks and concludes that ICRP models have not arisen out of accepted scientific method. Specifically, ICRP has applied the results of external acute radiation exposure to internal chronic exposures from point sources and has relied mainly on physical models for radiation action to support this. However, these are averaging models and cannot apply to the probabilistic exposures which occur at the cell level. A cell is either hit or not hit; minimum impact is that of a hit and impact increases in multiples of this minimum impact, spread over time. Thus the committee concludes that the epidemiological evidence of internal exposures must take precedence over mechanistic theory-based models in assessing radiation risk from internal sources.

3. The committee examines the ethical basis of principles implicit in the ICRP models and hence in legislation based on them. The committee concludes that the ICRP justifications are based on outmoded philosophical reasoning, specifically the averaging cost-benefit calculations of utilitarianism. Utilitarianism has long been discarded as a foundation for ethical justification of practice owing to its inability to distinguish between just and unjust societies and conditions. It may, for example, be used to underpin a slave society, since it is only the overall benefit which is calculated, and not individual benefit. The committee suggests that rights-based philosophies such as Rawls Theory of Justice or considerations based on the UN Declaration of Human Rights should be applied to the question of avoidable radiation exposures to members of the public resulting from practice. The committee concludes that releases of radioactivity without consent can not be justified ethically since the smallest dose has a finite, if small, probability of fatal harm. In the event that such exposures are permitted, the committee emphasises that the calculation of 'collective dose' should be employed for all practices and time scales of interest so that overall harm may be integrated over the populations.

4. The committee believes that it is not possible accurately to determine 'radiation dose to populations' owing to the problems of averaging over exposure types, cells and individuals and that each exposure should be addressed in terms of its effects at the cell or molecular level. However, in practice, this is not possible and so the committee has developed a model which extends that of the ICRP by the inclusion of two new weighting factors in the calculation of

effective dose. These are biological and biophysical weighting factors and they address the problem of ionisation density or fractionation in time and space at the cell level arising from internal point sources. In effect, they are extensions of the ICRP's use of radiation weighting factors employed to adjust for differences in ionisation density resulting from different quality radiations (e.g. alpha-, beta and gamma).

5. The committee reviews sources of radiation exposure and recommends caution in attempting to gauge the effects of novel exposures by comparison with exposures to natural radiation. Novel exposures include internal exposures to artificial isotopes like Strontium-90 and Plutonium-239 but also include micrometer range aggregates of isotopes (hot particles) which may consist of entirely man-made isotopes (e.g. plutonium) or altered forms of natural isotopes (e.g. depleted uranium). Such comparisons are presently made on the basis of the ICRP concept of 'absorbed dose' which does not accurately assess the consequence for harm at the cell level. Comparisons between external and internal radiation exposures may also result in underestimates of risk since the effects at the cell level may be quantitatively very different.

6. The committee argues that recent discoveries in biology, genetics and cancer research suggest that the ICRP target model of cellular DNA is not a good basis for the analysis of risk and that such physical models of radiation action cannot take precedence over epidemiological studies of exposed populations. Recent results suggest that very little is known about the mechanisms leading from cell impact to clinical disease. The committee reviews the basis of epidemiological studies of exposure and points out that many examples of clear evidence of harm following exposure have been discounted by ICRP on the basis of invalid physical models of radiation action. The committee re-instates such studies as a basis for its estimates of radiation risk. Thus the 100-fold discrepancy between the ICRP model's predictions and the observed cases in the Sellafield childhood leukemia cluster becomes an estimator of risk for childhood leukemia following such exposure. The factor is thus incorporated by the committee into the calculation of harm from internal exposure of specific types through its inclusion in the weighting factors used to calculate the 'effective dose' to the children in Sieverts.

7. The committee reviews the models of radiation action at the cell level and concludes that the 'linear no threshold' model of the ICRP is unlikely to represent the response of the organism to increasing exposure except for external irradiation and for certain end points in the moderately high dose region. Extrapolations from the Hiroshima lifespan studies can only reflect risk for similar exposures i.e. high dose acute exposures. For low dose exposures the committee concludes, from a review of published work, that health effects relative to the radiation dose are proportionately higher at low doses and that there may be

a biphasic dose response from many of these exposures owing to inducible cell repair and the existence of high-sensitivity phase (replicating) cells. Such dose-response relationships may confound the assessment of epidemiological data and the committee points out that the lack of a linear response in the results of epidemiological studies should not be used as an argument against causation.

8. In further considering mechanisms of harm, the committee concludes that the ICRP model of radiation risk and its averaging methods exclude effects which result from anisotropy of dose both in space and in time. Thus the ICRP model ignores both high doses to local tissue caused by internal hot particles, and sequential hits to cells causing replication induction and interception (second event), and merely averages all these high risk situations over large tissue mass. For these reasons, the committee concludes that the unadjusted 'absorbed dose' used by ICRP as a basis of risk calculations is flawed, and has replaced it with an adjusted 'absorbed dose' which used enhancement weightings based on the biophysical and biological aspects of the specific exposure. In addition, the committee draws attention to risks from transmutation from certain elements, notably Carbon-14 and Tritium, and have weighted such exposures accordingly. Weightings are also given to radioactive versions of elements which have a particular biochemical affinity for DNA e.g. Strontium and Barium and to certain Auger emitters.

9. The committee reviews the evidence which links radiation exposure to illness on the basis that similar exposures define the risks of such exposures. Thus the committee considers all the reports of associations between exposure and ill health, from the A-bomb studies to weapons fallout exposures, through nuclear site downwinders, nuclear workers, reprocessing plants, natural background studies and nuclear accidents. The committee draws particular attention to two recent sets of exposure studies which show unequivocal evidence of harm from internal irradiation at low dose. These are the studies of infant leukemia following Chernobyl, and the observation of increased minisatellite DNA mutations following Chernobyl. Both of these sets of studies falsify the ICRP risk models by factors of between 100 and 1000. The committee uses evidence of risk from exposures to internal and external radiation to set the weightings for the calculation of dose in a model which may be applied across all exposure types to estimate health outcomes. Unlike the ICRP the committee extends the analysis from fatal cancer to infant mortality and other causes of ill health including non-specific general health detriment.

10. The committee concludes that the present cancer epidemic is a consequence of exposures to global atmospheric weapons fallout in the period 1959-63 and that more recent releases of radioisotopes to the environment from the operation of the nuclear fuel cycle will result in significant increases in cancer and other types of ill

health.

11. Using both the ECRR's new model and that of the ICRP the committee calculates the total number of deaths resulting from the nuclear project since 1945. The ICRP calculation, based on figures for doses to populations up to 1989 given by the United Nations, results in 1,173,600 deaths from cancer. The ECRR model predicts 61,600,000 deaths from cancer, 1,600,000 infant deaths and 1,900,000 foetal deaths. In addition, the ECRR predict a 10% loss of life quality integrated over all diseases and conditions in those who were exposed over the period of global weapons fallout.

12. The committee lists its recommendations. The total maximum permissible dose to members of the public arising from all human practices should not be more than 0.1mSv, with a value of 5mSv for nuclear workers. This would severely curtail the operation of nuclear power stations and reprocessing plants, and this reflects the committee's belief that nuclear power is a costly way of producing energy when human health deficits are included in the overall assessment. All new practices must be justified in such a way that the rights of all individuals are considered. Radiation exposures must be kept as low as reasonably achievable using best available technology. Finally, the environmental consequences of radioactive discharges must be assessed in relation to the total environment, including both direct and indirect effects on all living systems.

2003 Recommendations of the ECRRThe Health Effects of Ionising Radiation Exposure at Low Doses and Low Dose Rates for Radiation Protection Purposes: Regulators' Edition Chapter 2: Basis and Scope of the Report

2.1 Objectivity The European Committee on Radiation Risk arose from a recognition among scientists, politicians and campaigners that there was considerable disagreement over the health effects of low-level radiation and the feeling that this issue should be explored on a formal level. The committee's remit was to consider all the available scientific evidence. In particular, the committee was to make no assumptions whatever about preceding science and to remain independent from the previous risk assessment committees such as the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the European Commission and risk agencies in any EU member State. The committee believes that in the search for scientific objectivity it should 'look out of the window', rather than following the trend of increasing dependence on processes of mathematical modelling. Thus the committee has considered the results of studies published in the peer-review literature and also reports, books and articles which have not been submitted for peer review. The committee believes that the approach adopted by scientific risk committees of only accommodating evidence with accurate dose-response data published in

peer review scientific journals has resulted in the propagation of a model which is increasingly seen to be unsafe. Furthermore, the committee believes that discussions in the area of radiation risk must involve all groups in Society. Therefore, although primarily consisting of scientists, the committee and its advisors include those physicians, non-scientists who must deal with medical problems of exposed persons. For example, risk assessment should include physicians trained in Public Health, Occupational Health Oncology, Paediatrics, and scientists trained in Genetics, Epidemiology and Biochemistry. These disciplines are not represented in the Main Committee of the ICRP. The regulations on membership as posted by ICRP includes: physicists, medical regulators, radiologists, biophysicists, etc. Persons who do not use radioactive materials in their employment are excluded. Among those included as advisors to the ECRR would be non-scientists such as risk sociologists, lawyers, politicians and members of non-governmental organisations and pressure groups.

2.2 Basis of the report The present report is intended to be accessible to and to inform decision makers who need to assess health risks to workers and members of the public who may be exposed as a result of practices which involve ionising radiation. It is therefore labelled a 'Regulators' Edition', the aim being to condense or review enough of the area for this process to be possible without being unwieldy. Future publications will deal in depth with the issues outlined here. The basis of the report is a perceived failure of the present radiation risk model (named here the ICRP model) to explain or predict real increases in ill health in a large number of groups exposed to ionising radiation at low doses. Most of the examples where this has occurred will be referred to in the body of the report but the position of the committee has been affected also by much that cannot be included, for reasons of space. This includes reports which have been published in the peer-review literature, and reports which have not, or which started life as television documentaries and ended as court cases. The committee has included consideration of those who voted with their feet and left areas where there were nuclear sites, regions which slowly became wastelands where only the poorest people could live and where the beaches were deserted by holidaymakers and fish were increasingly difficult either to catch or sell. It has included the tales of ordinary people who have been affected by man-made radioactivity, in India, Namibia, Kazakhstan, Nevada, Australia, Belarus and the Pacific Islands. For those who are prepared to read contemporary reports there are enough desperate stories. One example is that of weapons tests and the Australian Aboriginal people who were found dead in contaminated craters. Another concerns whole tribes in the Marshall Islands who had to abandon the Islands which they had called home for 3000 years.

2.3 Scope of the report The report will review the present methodology for assessing radiation risk. It will argue that

its dependence on averaging, both in the area of energy deposition in tissue in space and time and also its dependence on epidemiological studies involving external exposure has resulted in major errors in its quantification of risk from internal irradiation. It is intended that the report should convey sufficient evidence that the present radiological safety models are largely accurate for external irradiation situations involving doses greater than 100 mSv but break down where calculations involving averaging methods are used to examine non-uniform doses in microscopic tissue volumes. The report will examine the historical origin of the ICRP model and will review epidemiological evidence for its successes and failures. The report will consider the philosophical aspects of the science of radiation risk and make a distinction between the inductive and deductive approaches to establishing objective risk estimates. It will present evidence for quantitative ranges of error in the ICRP models as highlighted by various authors and studies and will assemble these into a set of hazard enhancement weighting factors which form the basis of a pragmatic interim approach to the problem of assessing radiation risk using the present units and quantities. Finally, the report will briefly outline some examples of the application of such a system for assessing radiation risk. A calculation of the mortality yield of the post-war nuclear age based upon ICRP and modified ICRP risk factors will also be presented. The approach is necessarily pragmatic. Data on radiation exposures and activities has been tabulated and recorded using units of dose devised from within the ICRP system: it is therefore necessary to provide factors which may be used with this system and this is what the committee has striven to achieve. These factors are provided as central estimates of hazard enhancement for certain types of exposure and may be used as multipliers of risk for the risk factors presently used by ICRP. However, the committee believes that the use of the average energy dose units Gray and Sievert places too many constraints on the science of risk assessment for internal isotopes and that a different, more rational system of assessing such exposures is required. Some suggestions are made towards achieving such a system.

2.4 References The committee carefully considered the question of whether the editors should attempt to reference every statement made in this Regulators' Edition. On the one hand, the ICRP, whose handbook ICRP90 this present volume is intended to supplant, contains no references. On the other hand, the more lengthy reviews of the United Nations (UNSCEAR) and the US Academy of Sciences (BEIR) carry select references which support their statements whilst omitting other references to work which either falsifies or does not support their statements. In addition, the committee was aware both of the constraints that would be placed on the size of the edition if all statements were referenced, and the loss of flow of the argument which would follow the considerable expansion of the text. As a compromise, the committee decided to attach a list of the main works on which its beliefs are

founded, without attaching each to some piece of the text. In addition, certain references are included where it seems particularly necessary to draw attention to a particular source.