

The 1984 SIEVERT LECTURE

SIEVERTS AND SAFETY†



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Abstract—The development of sound methods of radiation protection depended upon reliable dosimetry, both for internal and for external radiation. The proper safety of practices involving radiation exposures can only be adequately reviewed in light of the doses to which tissues are exposed by these practices, and of the types and magnitudes of the risks associated with these doses. Evaluation of risk is an essential step in the pursuit of safety.

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INTRODUCTION

THE development of sound criteria for radiation protection depended, in the early days of radiology, upon reliable information on the doses at which tissue injury was caused. This remained true during the whole progress of genetic, radiobiological and epidemiological studies of radiation effects. No valid estimates of the relative safety or risk of different levels of exposure could have emerged unless the standards of dosimetry had been clearly defined and similarly applied in different studies; and continuingly, the effectiveness of practical radiation protection relies on the regular monitoring or estimation of doses received from external or internal emitters, in the work place or in the general environment. The debt that we owe to Rolf Sievert is immense, for the strength and clarity of his pioneering work on the bases and practice of dosimetry; and the special unit of dose equivalent is aptly named.

The sequence of dates is compelling. In 1921 Sievert had calculated the distribution of γ radiation round Ra sources as used in medical therapy, and had published measurements verifying the validity of these calculations (Sie21). By 1925, his laboratory at the Radiumhemmet had developed mobile measuring equipment which made it possible to standardise dose estimation in different centres (Sie25). Hermann Muller's report 2 yr later (Mu27), of the induction of recessive lethal mutations in irradiated *Drosophila*, does not indicate the dose at which this effect had occurred; but 3 yr later he reported his dose rate as likely to have been about 80 R/min continuing to a total exposure of about 3400 R (Mu30). In 1930 also, Oliver demonstrated that similar effects were detectable down to 300 R (Ol30) and by 1948, Uphoff and Stern had estimated the frequency with which mutations were induced at exposures of 150, 50 and 25 R (Up49).

A similar progress in the quantitative radiobiology of somatic cells occurred during the same significant time period, when different laboratories could confirm or extend each other's results in the knowledge that they were working under similar conditions of exposure or dose. Lee's *Actions of Radiations on Living Cells* (Lea46) was published in 1946, and his references to work on the biological effects of ionizing radiation range essentially from 1923 on-

wards, with only 1 reference (Ch12) before that date.

RADIATION PROTECTION

This sequence of events gives us the context for the evolution of the recommendations and practice of radiation protection. The ICRU and ICRP were established, in 1925 and 1928, at the first 2 international congresses of radiology; and Rolf Sievert was appointed to membership of each Commission. It was not until 1934, in its fourth issue of recommendations, that the ICRP (then still named the International X-ray and Radium Commission) felt able to propose an occupational limit: of "0.2 international röntgens per day" as being an exposure to x rays which "the evidence at present available appears to suggest (as one which) a person in normal health can tolerate. . ." (ICRP34). Work was to be limited to 5 days a week (with "off days to be spent as much as possible out of doors"), and with "not less than 4 weeks holiday a year, preferably consecutively". (Product: 48 R/yr.) The same limit was applied to γ radiation from radium in the Commission's next report in 1937 (ICRP38).

It is significant that, in each of these recommendations, the "known effects to be guarded against" were injuries to superficial tissues, changes in the blood, and derangement of internal organs, particularly the generative organs. And that "the dangers of over exposure. . . can be avoided" by adequate protection and working conditions. By 1934, the induction of malignancies at high dose in man had been recognised for 30 yr (Fr02), and in animals for almost as long (Mari10). No adequate epidemiological studies had been made, however, of the effects of moderate organ doses. Martland's report in 1931 (Mart31) of sarcoma in dial painters, and earlier evidence of lung-cancer induction in uranium miners (Ro26), had not shown carcinogenesis to be occurring at such dose levels, and it still seemed likely that malignancies might only follow the gross and microscopically demonstrable tissue disruption that was caused by higher exposures. The risks to be guarded against, under normal working conditions, will have appeared to be non-stochastic rather than stochastic ones, although mercifully those egregious adjectives had not yet been misap-

propriated from the purer realms of mathematical thought.

Uncertainty as to how low a dose might be harmful was already evident, however, in the ICRP's cautious reference in 1934 to exposures which "the evidence at present available" appeared to suggest as being tolerated by persons in normal health. And, in the unavoidable interval between the fifth international congress in Chicago in 1937, and the sixth in London in 1950, much evidence had accumulated which changed the picture. The data of Uphoff and Stern (Up49) in 1949 had indicated an approximate constancy in frequency of induced mutations per unit dose down to 25 R in *Drosophila*. The papers of March in 1944 (Marc44) and of Dublin and Spiegelmann in 1948 (Du48), had shown the increased mortality from malignant disease in U.S. radiologists as following doses which could not be reliably estimated, but which were unlikely to cause the gross tissue damage which radiation-induced cancers had been supposed to follow.

At the sixth congress, therefore, ICRP referred in its recommendations (ICRP51) to "the increase in biological knowledge (having) brought a realisation of the importance of . . . carcinogenic and genetic effects (and having) provided more information as to the permissible levels of radiation." To the harmful effects to be considered, the production of leukaemia and malignant tumours were to be added, as were other deleterious effects including cataracts, and, curiously, obesity. While the recommendations still refer to the previous limit of dose rate as seeming to be "very close to the probable threshold for adverse effects", the suggested new maximum permissible exposures are described as "such as to involve a risk which is small compared to the other hazards of life" but to require that "every effort be made to reduce exposures of all types of ionizing radiations to the lowest possible level". ALARA and radiation risk comparisons are 24 yr old next month.

EPIDEMIOLOGY

Within the following few years, a number of important epidemiological surveys were published showing an increased frequency of malignant disease following only moderate doses of whole or partial body radiation: to the neck in

children in 1955 (Sim55), to the foetus *in utero* in 1956 (St56), and to patients with ankylosing spondylitis in 1957 (Co57). An increase in leukaemia was recognisable in Hiroshima by 1952 (Fo52), and of other malignancies in 1959 (Ha59).

Moreover, tentative estimates of the dose-response relationships suggested a "quadratic" relationship between leukaemia mortality and the mean bone marrow dose in the spondylitics, at moderate dose levels, and with the estimated dose in different groups exposed in Hiroshima (UNSCEAR58). The probability of a subsequent increase in childhood cancer appeared to be proportional to the number of x-ray films used during the pelvic examinations of the mothers during their pregnancies. Lewis's suggested estimates of the leukaemia risk per unit dose from various sources appeared in 1957 (Lew57). Bond and his colleagues showed in 1960 that the increased, or accelerated, mammary cancer incidence in Sprague-Dawley rats was proportional to the dose delivered (Bo60). And in genetics, the findings of Glass and Ritterhoff appeared in 1961 suggesting a dose-response relationship for mutations in *Drosophila* that was consistent with linearity down now to 5 rad (Gl61). During these years ICRP, which had been under Sievert's perceptive chairmanship since 1956, reflected the emerging evidence in its statements, for example in 1958, that "the most conservative approach would be to assume that there is no threshold and no recovery (from radiation exposure, and that if so) even low accumulated doses would induce leukaemia in some susceptible individuals and the incidence might be proportional to the accumulated dose" (ICRP59); and in 1962, that "any exposure to radiation may carry some risk" (ICRP64).

In this context, there was reference also to balancing "as far as possible the risk of the exposure against the benefit of the practice", so that this supposedly recent innovation also has already celebrated its 21st birthday, and has now evidently come of age.

ZERO THRESHOLD AND RISK

With the explicit abandonment, at least for radiation protection, of the idea of a threshold dose or dose rate below which no harmful

effects would be caused, the importance of secure dosimetry and risk estimation are greatly increased. It was no longer a case only of determining the dose levels above which certain effects are liable to occur, and the probability of these effects if such levels were exceeded. If no threshold can be assumed to apply, it becomes essential to achieve some estimate, and the best currently available estimate, of the likely frequency of various effects that might result from the low doses received occupationally, or the very low doses received in the general public. We are involved immediately in a change in kind, and not merely in a change in magnitudes and arithmetic, in our approach to risk evaluation. It is no longer a question of safe or not safe; it is a question of how safe. We are not asking whether a given exposure is permissible, but how permissible it is in given circumstances; and this is no longer a matter only of scientific evaluation. Yet no recommendation can honestly be made on the appropriate safety of dose limits, or of the average dose rates that result from their observance, without evaluation both of the types of risk and of the size of these risks that are incurred.

This problem does not, of course, arise only with radiation as an environmental contaminant. We have all lived with its implications for 20 yr or more, but are only now seeing the embarrassment when it is gradually appreciated that for Pb, for asbestos fibres, and perhaps for many chemicals there may be no safe threshold below which contamination levels are harmless. Radiation protection has had many advantages: not only in having a defined and measurable quantity that is relevant to causation of effects, at least on the cellular scale and increasingly on the molecular scale: not only also in the large quantity of human epidemiological evidence that is—unhappily—available as a source of quantitative risk estimation. We are, I think, fortunate particularly that protection and risk estimation have been based for almost half a century on a recognition of the importance of late-coming effects, and not merely on the exposures which are low enough to prevent early or so-called acute effects. The chemical toxicologists deserve our sympathy in the daunting task of estimating what might be the effects, let alone the frequency of effects, within the first

25 yr after exposure to any of a hundred or more new chemicals per year.

But this priority in radiation risk estimation does mean that those concerned with radiation protection must bear much of the brunt of advancing what to many people are relatively new ideas. If a procedure cannot be made entirely safe, how safe should it be? The need to minimise risk has been a familiar one for centuries. The problem of developing a coherent and quantitative policy on acceptable levels of risk is more recent. It is the more difficult when the source of the risk is an unfamiliar one, and when the estimate of the risk must in many circumstances be predictive, rather than based on long recorded experience.

In these conditions the size of the risk must surely be relevant, as well as the nature of the risk, and whether it is of accident, disease or disability. It must ordinarily be as stupid to make decisions solely in terms of the nature of a risk, regardless of whether it is very small or very large, as it is to make the decisions solely on the size of the risk regardless of its nature. And, perhaps, to ignore both size and nature and classify situations simply as safe or unsafe must be a form of synergistic stupidity.

But the acceptability of a risk in terms of its nature, its size and the way it is imposed, is ultimately a societal rather than a simply scientific one. And if so, how should the question be put to society for review and decision; and to what organ of society? In particular, what is the fairest and most helpful way to ask what level of risk is regarded as acceptable in a given situation? It is likely to be both unfair and unprofitable to ask directly for a simple numerical answer—for example, for the fatal accident rate which should not be exceeded. Our educational systems do not train us to think easily in high negative powers of 10 or to recognise their significance if we do. Admittedly the Royal Society of London, which can think in such terms, has recently published a report, *Risk Assessment* (RS83), in which it is suggested that continuing annual risks of death of less than 10^{-6} , and certainly of less than 10^{-7} , are ordinarily not regarded as a basis for action, whereas if such risks of fatality are greater than 10^{-3} , and certainly if greater than 10^{-2} /yr, they are usually regarded as unacceptable.

INTERCOMPARISON OF RISKS

In general, however, it must be more fruitful to seek opinion on new risks, by comparing the estimated size of these risks with that of the risks already incurred in existing and familiar situations.

If so, however, we have several immediate difficulties. The risk in the comparison situation should be of the same kind, and imposed in the same way, as those on which we seek a decision. The very familiarity of the comparison situation, however, will tend to make its risks seem less important than qualitatively and quantitatively equal risks in a new situation; and particularly so if the latter must necessarily be estimated predictively, rather than known from long recorded experience. Moreover, in comparing risks of radiation exposure with those of other agents in the working or general environment, it is difficult to compare like with like. Increased mortality from particular types of cancer have certainly been detectable in various industries, or sections of industries, in the past (Po74). These increases have, however, ordinarily been detectable only at levels greatly above any that are likely to result from radiation exposures controlled by current dose limits. Such industries, therefore, give no adequate criterion of the efficiency with which malignant disease should be prevented in current working conditions.

Therefore, comparisons often have been made between the risk of death from all causes, whether by disease or by accident, in a range of conventional industries and in those involving radiation exposure. Indeed, the need to see the possible risks of occupational exposure to radiation in the perspective of all other occupational risks has been largely responsible for the comparative study of occupational mortalities under a variety of conditions. Records of accidental death rates in different industries are available for many years in a large number of countries; and, with less reliability, for those diseases which have been recognised or admitted to be of industrial origin. One of the earliest inter-comparisons of such fatality rates, however, and of those that might result from radiation exposure, was that of Farmer in 1961 (Fa61), and many such analyses have been made since then.

Such comparisons have obvious importance

in setting a scale of reference, and in indicating the very different degrees of safety or risk in present conventional industries. Their annual risks of accidental death are found to vary over about 3 orders of magnitude (RS83), from a few such deaths per year in every million workers at risk, to a few thousand. And certainly the fact of any occupational death has compelling importance, whatever the mode of death or the time of life at which it occurs.

SUMMATION OF RISKS

As a sole criterion for comparing the risk of different occupations, however, the mortality rate from all causes is inadequate. It ignores the detriment from the far greater number of non-fatal accidents causing either temporary disability, or a greater or lesser degree of permanent disability. It ignores the detriment from non-fatal illnesses, which is substantial in a few industries. And, as regards the effects of radiation exposure, it ignores the detriment due to induction of curable cancers and developmental defects, and it is necessarily equivocal in its evaluation of inherited defects of differing severity.

Two solutions could be suggested. On the one hand, a complete listing could be given for each industry of every severity of accident, or type of disease or disability, with the estimated risk of occurrence of each. The lists would inevitably be long and medically elaborate, and inter-comparisons would probably be hindered rather than helped by the detail and clinical complexity.

The second alternative is that of attempting to aggregate the detriment incurred in each industry or situation into a much more simple index of the total harm, by finding some measure of each type of harm which could properly be summated to indicate the overall safety or risk of the industry. Any such aggregation could only demonstrate the approximate ranking of the safety of different working conditions. It could still, however, give a sufficient basis for distinguishing the safer industries from the more hazardous ones, and for indicating the very safe and the very hazardous, provided the basis for aggregating different forms of harm was an appropriate one.

One such basis which appears useful, at least

as a first approximation, is that of the lengths of time lost from full health or activity, or of the length of the normal life expectancy lost, as a result of each form of injury or disease (ICRP77). In a wide range of industries, records are available of the frequency of non-fatal injuries, and the total lengths of working time lost as a result of them; and also of the ages at which accidental deaths occur. For radiation exposure, UNSCEAR and ICRP, as well as IRPA, have published extensive data from which the risks of different forms of disease or disability per unit dose can be assessed, and the losses of life expectancy and of normal health assessed. UNSCEAR has recently attempted also the same type of assessment for the variety of inherited defects which may be induced by radiation (UNSCEAR82).

Any such aggregation in terms of the lengths of time lost must still involve numerical weighting factors to differentiate between, for example, the detriment per month in hospital owing to a broken leg and that per month of life lost owing to a broken neck. Nor is the average period of 30 yr lost owing to an accidental death at work necessarily 3 times as detrimental as the average of 10 yr lost owing to a fatal cancer induced, after a typical period of latency, by radiation exposure at work (ICRP77).

But surely it is just these problems of the relative weight to be put on different effects of occupational or other exposure, which are at the heart of the questions on which we are in any case seeking an answer from the community. And we are, I think, most likely to obtain a considered judgment and a responsible opinion on them, if we offer for review a suggested method of comparison and definite proposals for the weights that might be attached to different effects; so that both the comparison and the weighting factors can then be debated, and either agreed or appropriately revised. At present our review of the weight that people attach to different forms of risk—the numerical study of perceived risk—is still in its infancy; and in some instances in its infancy also as regards the design of questions and the choice of the populations studied. It is important to examine further the public appraisal of risks when both the size and the nature of the risks are taken into account together.

I think we must recognise also that we are examining particularly the risks of radiation in order to assure ourselves that our measures of radiation protection ensure adequate safety. We have a linguistic problem here—at least in my language. We can speak of a risk of 1 in 50,000/yr, but not of a safety of 1 in 50,000/yr. Yet when we write of a situation or a job as involving an annual fatal risk of 1 in 50,000, a reader who is not by training or by habit particularly numerate, will tend to retain only a message that the situation involves risk and should therefore be rejected; and that if a risk needs to be examined in this way it must be large. It may be one of the values of the increasing public review and discussion of the magnitude of various kinds of risk, that a better perspective will emerge on which of the risks which surround us can truly be recognised as minor ones, and which are ones with which the community should be most concerned in producing a safer environment.

Sievert's life and his genius were devoted to ensuring a proper safety in the uses of radiation. His work gave us a firm basis for evaluating radiation doses and risks, and for seeking to maintain and improve that safety; and I am greatly honoured that you have invited me to join you in commemorating his name and his work in this outstandingly important field.

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