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BASES FOR ESTABLISHING RADIATION EXPOSURE LIMITS

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R E F E R E N C E S

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BASES FOR ESTABLISHING RADIATION EXPOSURE LIMITS

It is an essential step in the large scale development of any new technique that the safety of the procedure shall be properly reviewed. Certainly this has not always been so. For many of the processes which our culture uses, or on which it depends, we have had to learn the hazards the hard way - from the earliest investigations of which red berries were fatal to eat, not by biochemistry but by watching the more enterprising members of the tribe, down to the latest studies of the cost in deaths from bronchitis and pneumonia of a week of good rich London fog of the 1940's and 50's.

But in radiation protection we have been fortunate. Very early on, in fact within 7 years of Roentgen's discovery of X-rays, and the Curies' discovery of radioactivity, in 1895, the hazards were recognised - von Frieben related a cancer of the skin to the irradiation of the hand.(1) So that when the first reactor went critical 35 years ago, there was already a background of several decades of close and critical study - not just of the types of harmful effects that might be caused by radiation, but even - to an increasing extent already at that stage - of the frequency with which they might be caused by a given radiation exposure. The International Commission on Radiological Protection was set up almost 50 years ago, at that time of course primarily to advise on the proper protection of patients exposed to radiation, and of the staff administering the tests or the treatments. The task became vastly larger and more complex in detail, but no more difficult in principle, with the great increase in the number of ways in which people might be exposed to radiation, whether in their occupations or in the environment; but this was still at first a matter of deciding what dose, what exposure, it was safe to receive, and what dose it was dangerous to exceed; and so to plan the safety of the developing techniques.

The newer aspects that I wish to discuss completely altered this simple philosophy. For it became clear - first in genetics, and then increasingly in the study of somatic effects of radiation - in the harm done to the irradiated individual himself rather than to his descendants - that even the smallest doses might involve some, correspondingly small, probability of harm. This did not need to be proved. For protection purposes, if it could not be excluded, as a reasonable possibility, then we were faced no longer with a question of what dose was safe; no dose could be assumed to be entirely safe. It was a question now of what dose was safe enough - a much more difficult question to answer.

Difficult, because it had two quite separate halves. Firstly, how safe is any given dose; numerically, what risks does it carry? And secondly, how safe do you want to be?

Let me take the second half first. Obviously, as safe as it is practicable to make it. If any element of radiation exposure involves - or may involve - some element of risk, then clearly all unnecessary radiation exposure should be eliminated. The job to be done should, from the health and safety point of view, be done in the way that involves the least radiation exposure to people, whether in the working or in the general environment - and when exposure is unavoidable it should be fully justified, and more than justified, by the value or the necessity of the job. Justification of the exposure, and optimisation of conditions to eliminate unnecessary exposure and to minimise necessary exposure; these are essential aspects of any protection recommendations. But there are still two things missing. Firstly, how low should the risk be kept - for example, as a component of occupational hazard. Or in other words, what degree of safety in a quantitative sense implies a safe industry. And, secondly, what absorbed dose in human tissue corresponds to this degree of safety. Given that all exposures should be minimised, what is the limit that even so they should never exceed?

The other part of the question, on the quantitation of radiation risk, involves a straight radiobiological evaluation on which I wish to give some figures. But the first is an exercise in public opinion, on which I can only give a personal view. What is a safe occupation? Well, no occupation is safe in the absolute sense, but the levels of safety in different accepted and conventional occupations vary very widely - at least by a factor of 1000 as judged, for example, by the over-simple, but still quite important criterion of the number of accidental deaths attributable to the occupation per year and per million employed. The figures in each are reasonably stable year by year, falling perhaps by ½ or 1% per year but characteristic of the particular occupation[2]. And ranging down to a few deaths per million per year, and up to a few hundreds, or occasionally even to a few thousands of deaths per million per year - an immense scale of difference, and I think perhaps a bigger range of difference than is commonly realised. And this perhaps is an outline of the answer to the first question - how safe is safe enough, given that nothing in life is completely safe. No reasonable man would describe an industry as safe enough if its risk rate were in the thousands, with thousands of deaths from occupational causes per million employed per year; and probably not if the risk rate were in the hundreds. But I think he does so regard the industries whose rates are in the tens - the factories and light engineering.

Of course, there is a lot of difference, and potentially of acceptability, between the accidental death in industry that a man feels rightly or wrongly, that he is skillful enough to avoid - it will always be Fred, not me, that falls off a ladder - and the fatal malignancy developing 30 years later (although that time interval is itself a benefit) as a result of conforming to the regulations and keeping below the dose limits. But, it is necessary that, as a strictly medical and public health matter, the health statistics of the atomic energy industry shall conform and continue to conform, to good criteria of safety. This will be so if the dose limits, and the protection procedures to ensure that average exposures are held well below these limits, are so set that the purely radiation risks, added to any other risks of the employment, keep the total risk low on this list of risks in existing occupations - at least below the hundreds and properly down into the tens.

So the quantitative evaluation of risk is critical. Critical and difficult, because this is a situation in which the estimate must be predictive. It is not good enough to wait and see how the statistics work out - and this should never be regarded as good enough for a large, new, important and developing industry. But here it is unacceptable for two further reasons. Firstly, it is now clear that the risks to the exposed individuals are essentially confined to the possible occurrence of malignancies - of leukaemia or of cancer - and that these diseases, if they occur, only develop many years or decades after the exposure which is responsible for their induction - with an average interval in the region of 10 years for leukaemia and probably of more than 25 years for other malignancies.(3) So it is clearly inadequate to wait and see. But also, if any such malignancy does occur, it is indistinguishable from any naturally occurring form of the same disease - indistinguishable except statistically. And it is simple to show that it would require the full ascertainment of all deaths from malignant diseases from many tens of thousands of people studied over several decades, and a proper comparison with a comparable and unexposed population - even to detect statistically, that an increase in the sort of size that we have been discussing, had taken place.

But the task of prediction - of estimating the frequency (or the maximum likely frequency) of cancer induction, or of leukaemia induction per unit radiation exposure or tissue dose in man - this difficult task has been progressing remarkably fast - as based on epidemiological surveys: surveys of patients treated by radiotherapy at known dose and followed fully for 20 or 30 years to detect any excess occurrence of cancer in the irradiated areas; surveys in great detail of the survivors of the atomic bombing at Hiroshima and Nagasaki; surveys of patients who had received repeated diagnostic chest X-rays in the management of their diseases; surveys of a Pacific Island population exposed accidentally to local fallout from a nuclear weapon test in 1954 [and of uranium miners exposed to radon.] Inevitably (and fortunately) the information is limited in amount, and usually in precision, because there are - again fortunately - few human populations of known size exposed at known dose, and followed for the prolonged periods needed even for partial ascertainment of any tumours induced by the exposure. And the information must be obtained in man, if the estimates are to be numerically applicable to man: studies on irradiated experimental animals have shown large variations in the frequency with which a given type of tumour is induced from species to species, and even from strain to strain within the same species.

Moreover, the need is not merely for an estimate of the total risk of human irradiation. For many forms of exposure, both occupational and environmental, as you know, radionuclides are selectively concentrated in particular body tissues or organs; soluble plutonium in bone and liver, radioiodines in the thyroid, inhaled insoluble particulates in the lung and its lymphnodes, and unabsorbed ingested nuclides irradiating particularly the lower gut. We need to know, therefore, not just the sensitivity of the body as a whole for cancer induction, but that of any body organ or tissue which may be selectively irradiated. And it is a remarkable fact that approximate estimates of this sort - approximate but of adequate accuracy for protection purposes - have been obtained for 15 to 20 different body organs or tissues; and, for the very reason that their sensitivity has been detectable, these are likely to be the tissues which are most important in radiation protection.

This information allows appropriate limits to be set for the intake into the body of particular radionuclides, according to the organ which they selectively irradiate; or rather, and better, according to the estimated hazard resulting from all the organs they significantly irradiate - depending upon their concentration in each of these organs (or the irradiation from adjacent tissues) and the estimated sensitivity to carcinogenesis or any other effects for each of the organs. This is clearly more realistic than the artificial simplification that it was only the organ of highest irradiation that was counted - the "critical organ". Nor is the procedure more complex in actual use, since the calculations of uptake, retention, crossfire from other tissues and differential radiosensitivity of different organs, are built into the initial derivation of the intake (conveniently the annual limit of intake) that will correspond to the standard level of risk. For it is rational to adopt one standard level of risk that would correspond to the limit of intake or exposure, whatever the mode of intake or exposure, and whatever the organs irradiated. The procedure concedes the reasonable proposition that the level of safety corresponding to the limit for any nuclide or form of exposure, shall be the same whether from exposure of skin alone, a group of internal organs, the whole body uniformly, or any particular tissue that may be involved.

It also follows, as again appears reasonable, that the risk of whole body exposure should be equal to the sum of the risks from each organ so exposed. Here the genetic risks from gonadal exposure clearly enter the picture, and some comparison has to be made between the total impact of genetic injuries from a given exposure, and the totality of risks to the exposed individual himself - a comparison involving judgements that are more difficult than in the case of different harms to the individual, but a value judgement that has to be made if dose limits are to be set. And effects with a threshold (below which the effect does not occur), as with the causation of opacities of the lens of the eye, can similarly be taken into account. The underlying assumption - of the separate additivity of the frequency of effects in different tissues - would certainly not hold at high dose, since impairment of the function of one organ would affect the performance of another, and a high frequency of one fatal condition would reduce the death rate from another. At the low doses involved in protection work, however, it is a reasonable approximation that the frequency of effects on individual organs add to produce the total frequency, that the total risk depends upon the totality of organs irradiated, and that the body behaves, for this purpose, as the sum of its parts.

This immediately introduces a coherence into the dose limits taken for the whole body, and for its various organs if selectively irradiated: a spurious coherence, admittedly, to the extent that organ sensitivities to carcinogenesis are only known approximately and in part - but certainly preferable - once the necessary information has become available-to dose limits which imply an equal risk from irradiation of the whole body and of only one organ or part of the body. Preferable also to a system which computes only on the one organ most highly irradiated. And a system which, as the basis for calculation, allots to the whole body a weighting factor, an importance, of unity, and then gives individual weighting factors to each organ or tissue according to their estimated contribution to the total harm of whole body irradiation.

But no system is stronger than its component parts. Some of the estimates of risk for particular tissues are inexact (indeed many are very inexact, and all are moderately inexact), some depend essentially on high LET radiation exposure of uncertain relative biological effectiveness, some rely on obviously imperfect comparison populations, although in a number of cases estimates from different sources are mutually consistent within their accuracy of determination. And all - or almost all - depend on hazard detected following high dose exposure, from which that at low dose has to be inferred, with some likelihood of over-estimating the risk per rad if the inference is based on linear extrapolation, particularly for radiation of low LET. But it is a paramount point of importance, often forgotten in the heat of crisp critical argument, that the right development of protection recommendations, and the right estimation of numerical limits of exposure, depends on using the best and fullest information available at the time, and not of perfect information being available. If the facts are clearer this year than they were last year, and show the need for significant revision, that revision does not become inappropriate merely because the facts will be clearer still next year. I believe that the human epidemiological evidence of the levels of hazard to be expected from moderate radiation exposures, allows the limits of exposure to be set on an increasingly secure basis and according to the increasingly coherent system which I have attempted to describe.

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