Judgement in Achieving Protection Against Radiation

by Lauriston S. Taylor

IONIZING RADIATION AS A TOXIC AGENT

Ionizing radiation has been known to man for nearly eighty-five years and for only a few weeks less than that time it has been recognized that if people are exposed to enough ionizing radiation they may suffer injury of an obvious and definable nature. What is not known is whether there is some lower limit to the exposure below which man will not suffer injury and above which he will. There is nothing especially unusual about this state of affairs, except for one characteristic: compared with most other possibly injurious agents, ionizing radiation (referred to hereafter as radiation) has always been a part of our natural environment. Even though recognized as a part of the environment, there is no known way in which its presence can be completely eliminated or even significantly modified or counteracted. Man has always lived in a somewhat hostile environment. But the great difference between man and other animal life is that in most situations man has been able to learn to live with, to control, to modify, and, in some instances, to eliminate environmental hazards.

For all practical purposes, radiation is just another toxic agent or pollutant. Basically, it is not really very different from many other toxic agents as to its effects and as to how it can be avoided or controlled. However, the treatment and control of radiation as a toxic agent have been far better understood and more strictly applied than for chemical or biological agents and it is important that we develop some appreciation of this fact.

Radiation is claimed to have an insidious aspect in that it cannot be seen, tasted, felt or smelled. However, the same limitations apply to a host of other toxic agents with which, for better or worse, we live. Radiation may produce cancer and have adverse genetic effects and there may be long latent periods between exposure and effect. There is nothing unique about this; many chemicals and environmental conditions work similarly.

On the other hand, in contrast to many equally dangerous toxic materials, radiation can be readily measured and controlled at levels thousands of times lower than have ever been shown to be deleterious.

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This must not be misinterpreted as downgrading the potential risk associated with the use of radiation or the need for protection against radiation, the purpose is to put the radiation problem into some kind of reasonable balance and acceptance with respect to many other hazards introduced by agents which we accept as essential to our way of living. But here we are faced with the real problem. How do we decide what is in reasonable balance and who makes these decisions? The answers to these two questions are certainly not fully resolved and the day is not seen when they will be to the satisfaction of everyone.

VALUE JUDGEMENT IN ESTABLISHING PROTECTION STANDARDS

Given the impossibility of experimentally establishing a 100% safe upper limit of exposure, any solution to the radiation protection problem involves a blending of science and technology on the one hand and moral, social, economic and political *value judgements* on the other Ref [1] This was clearly recognized as far back as the early 1920s, when the first attempts were made to establish a radiation dose that might be acceptable in terms of biological effect.

To demonstrate the problem, it will be instructive to go back to the origin of our radiation protection standards and then see how our current standards derive from these early concepts Although this takes us back more than fifty years, it was not until 1949 that the first clear statement describing a permissible occupational exposure Ref [2]* was developed by the National Committee on Radiation Protection (NCRP)** and a year later was adopted, with some refinements in language, by the International Commission on Radiological Protection Ref. [3]. The NCRP statement was as follows: "Permissible dose may then be defined as the dose of ionizing radiation that, in the light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his lifetime. As used here, 'appreciable bodily injury' means any bodily injury or effect that the average person would regard as being objectionable and/or competent authorities would regard as being deleterious to the health and well-being of the individual " *This statement centres around issues of judgement.* The question, still unanswered, is how to define what would be permissible or acceptable or appreciable.

ORIGIN OF RADIATION PROTECTION STANDARDS

For many years, up to about 1930, a clinical dose of radiation was expressed in terms of what used to be described as a biological unit. It was called the "threshold erythema dose" (TED). By experiment and clinical experience, it was the single dose of X-rays necessary to cause a skin erythema (a reddening of the skin) and was defined in terms of operating details including size of the X-ray field, tube current, tube voltage, distance between tube and patient, and time of appearance of reddening. Other doses were then described in terms of fractions or multiples of the skin-erythema dose. However, because of the many biological factors involved in a skin reaction, this evaluation of X-ray dose was subject to deviations as large as 200 or 300 per cent among different observers. The same observer could often repeat his results within 50% or even 25%

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* See preface, page v in reference [2] and page iii in reference [13]

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In 1925, Mutscheller in the USA Ref [4], using improved X-ray absorption data for walls and barriers, made computations of the fractional TED at the positions of operators in a variety of therapeutic and diagnostic clinics that were then regarded as well-designed and shielded. At the same time, he observed that individuals working in these areas showed no untoward effects when they were exposed to levels which were calculated to be of the order of one TED distributed over a year's time. On this basis, he recommended a "tolerance dose" of 1/100 of a TED/month (approximately 1/10 TED/year) as "safe" for radiation workers. The important point to note here is that he was basing his recommendation on a lack of observed effect; he was applying *his judgement* that if 1 TED/year resulted in "no effect", 1/10 TED/year should certainly be tolerable It was the first of many examples of judgement being applied in the absence of information, and followed the general principle used in toxicology.

Quite independently, Sievert in Sweden was carrying out a similar study, comparing the exposure in a number of well-shielded radiation clinics with the exposure from natural background radiation Ref. [5]. He estimated that without any allowance for recovery it would take somewhere between 1000 and 10 000 years exposure to receive a skin erythema dose from natural background radiation. On the basis of the lower figure, he made the *technical judgement* that 1/10 of a skin erythema dose per year would be acceptable for radiation workers

Another study, carried out independently, although a year or two later, was the work by Barclay and Cox in the UK Ref. [6] and again involved dose estimates made under typical operating conditions. In their case, they had two individuals whose exposure over a six-year period they felt could be evaluated within the uncertainty of all of their other measurements While expressed somewhat differently from the two earlier workers their results could be converted to skin erythemas and interestingly enough were *judged* to be of the order of 1/10 of a skin erythema dose per year. (For more detailed discussions see Ref. [19])

Now one would be very tempted, upon looking at this information, to feel that three experiments carried out independently in three different countries, and all arriving at the same apparent answers, would lend credence to the absolute significance of the final result. However, *pure judgement* was the only common factor in the three studies contributing to their arrival at the same result.

NUMERICAL RADIATION PROTECTION STANDARDS

The problem of trying to find a measurable value for a tolerance dose was further complicated during this period by the lack of any agreed system of quantities and units for the measurement of ionizing radiation. Immediately prior to this, various attempts to evaluate an erythema dose in terms of "roentgens", (a term which meant different things to different people) were being made by a number of observers. In 1925, Meyer and Glasser in the USA arrived at a value of about 1300 roentgens (with backscattering) as the amount of radiation needed to cause a threshold erythema Ref. [7]. In 1927 Kustner in Germany, following the circulation of an elaborate questionnaire to a dozen or so of the better radiation institutes, arrived at a value of about 550 roentgens for a skin erythema dose where the measurements were made free in air (without backscattering) Ref. [8]. Both observers called attention to the many variables involved in their determinations.

The values reported to Kustner varied from 400 roentgens on the low side to 650 roentgens on the high side, and one observer reported a range of observations from 450–625 roentgens. It is clear that there was nothing very accurate about the overall result but as a matter of *judgement*, Kustner's value of 550 roentgens measured in air was generally accepted.

The first daily tolerance dose, expressed in roentgens, was put forward by the NCRP in early 1934. It was based upon Mutscheller's suggestion of 1/10 of an erythema dose per year Ref. [9]. Kustner's value of 550 roentgens (measured in free air) was rounded out to 600 roentgens, the number of working days in a year was taken as 250 and this calculated out to a value of 0.24 roentgens/day But because any such number would appear to have significance beyond the value of the basic data, and since the errors in the basic data were so large, this was rounded down to 0.1 roentgen/day (free in air).

About six months later the ICRP went through a similar exercise, arriving at a value of 0.25 roentgen/day. This was rounded down to 0.2 roentgen/day Ref [10].

It is important to note that we had now, for the first time, arrived at what appeared to be a quantitative value for a permissible radiation dose for radiation workers It should be further noted that all values for a permissible dose for radiation workers, up to today have been derived on one basis or another from the 1934 proposals.

However, it is not really as bad as it sounds because, since the first numerical standards were put forward in 1934, no injury or specific effect has been observed among the large number of people who might have been exposed to such levels of radiation.* For all we really know today, we may be grossly overprotecting ourselves at great cost or at the sacrifice of important benefits to man. It is not likely that we are seriously underprotecting ourselves. It is therefore crucial to our understanding to realize that any translation from that early background to our present system of numerical standards has been derived on the basis of the *exercise of judgement* – probably the best judgement that has been available to deal with the question.

The first protection standard for internal emitters (radium) was proposed in 1941. On the basis of then very limited evidence, the NCRP recommended that radium workers not be allowed to accumulate a body burden of more than 1/10 microgram of radium Ref. [11]. It was not until a number of years later that the validity of this recommendation was convincingly evaluated by the work of Evans Ref. [12] and others who, indeed, found no cases of identifiable radiation injury in individuals who had body burderns of less than 1/10 microgram of radium. It turns out that a body burden of 1/10 microgram of radium would deliver a dose to the bone of the order of 25 rem/year.

The next major step occurred in 1949 when the NCRP reviewed the whole radiation exposure problem because of the enormous changes expected to take place as a result of the development of atomic energy. Primarily because it was expected that many more people would be exposed in a wide variety of ways to many different kinds of radiation, the NCRP recommended lowering the permissible dose for radiation workers from 0.1 roentgen/day to 0.3 rem/week, a factor of roughly 2 Refs. [9], [13].

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* This statement is made keeping in view the general lack of acceptance of the overall Mancuso-Stewart studies

It must be noted here that this change in permissible dose was made without a single observation of injury to anyone exposed at the earlier levels which might have been as much as 0.1 or 0.2 roentgen/day. The NCRP basic definition for permissible dose was that quoted above Ref. [2].

As events have developed, there were further lowerings of the permissible dose level for radiation workers to the point where even if there was some minor abuse of exposure limitations by industry it was believed that the possible effects would be unimportant.

Again, these were matters of *judgement* and completely without scientific or specific medical evidence.

This raises another issue that is poorly understood by the public and technical communities alike. No matter what levels of exposure are set by regulatory bodies, industry, as a matter of practice, sets its administrative permissible levels substantially lower so as not to risk any chance of exceeding the "official level". This practice has led to a ratcheting situation where each time, and for whatever reason, there may be some pressure to lower the exposure levels it can usually be shown "that this would not exert any hardship on industry because they are already maintaining lower exposure levels".

A next important step occurred in 1956 when, reacting to the concerns about the possible effects of world-wide fallout from weapons testing, first the British Medical Research Council Ref. [14] and then the US National Academy of Sciences Ref. [15] drew new attention to the possible genetic effects of radiation. Following this, both the International Commission on Radiological Protection Ref. [16] and the National Committee on Radiation Protection Refs. [17],[18] recommended lowering the permissible dose to the gonads of radiation workers to a value of 5 rem/year. Again, there had been no direct observations of genetic or somatic harm from low levels of exposure on either laboratory mammals or the human population.

The original recommendation of the National Academy of Sciences in 1956 had been based mainly on some early experiments with fruit flies which showed certain genetic changes after exposure to high doses of radiation Ref. [15]. In part, their recommendation also appeared to have been an overreaction to a public clamour over fallout. Within 5 years, better experiments on animals contradicted the original basis for the Academy's recommentadions. But by that time it was too late to even consider reverting to the pre-1956 standards and they remain in effect today. Regardless of technical consideration it is very difficult politically to relax a protection standard of almost any kind.

It must be re-emphasized that the danger from which these elaborate precautions are intended to protect us is purely hypothetical at the low levels of exposure of today. Moreover, it should not be forgotten that the numbers used up to this time relate back directly to the uncertainties of the skin erythema dose and the conflicting measurement technologies of the 1920s.

EXPOSURE OF POPULATIONS

There was one further step in the development of radiation protection standards. By the late 1950's there was growing public concern about radiation hazards and great emphasis was placed on the reduction of radiation exposures, especially of the population as a whole. It should be noted that where the exposure allowed for individual radiation workers was 5 rem/year primarily for genetic reasons, the corresponding dose limit for the individual in the population was 1/10 of that, or 0.5 rem/year Refs. [16], [17], [18]

By the end of the 1950s, an increasing amount of biomedical data on the effects of large exposures of radiation had been developed Much of this came from the analysis of the experience of the Japanese survivors and from delayed effects resulting from radiation therapy. It was valid information for large doses and high dose rates, where it was found that there appeared to be a proportional relationship between the magnitudes of these exposures and their effects

The situation is very different with regard to established dose effects in the region below, say, 5 rad. The state of our knowledge can be summed up very easily: despite many millions of dollars worth of experimental studies carried out the world over, and despite many attempts at the clinical level, no one has yet been able to establish a dose-effect relationship for man in this low dose range. On the contrary, there is a tremendous amount of information in the form of negative results based on doses to radiation workers and a few others at levels up to 1 or 2 rad per year, and, less frequently, still others at levels up to 5, 10 or even 15 rad in a year The amount of such experience with large numbers of people is enormous and it must be given substantial weight, even though the results are negative. At the same time we must be prepared to answer the argument that the reason why we cannot find any direct or indirect effects is because they are too small or occur too infrequently That is, the effects are buried in the "noise" of natural occurrences.

This may well be the case, but of course, it is also part of the answer If the effects cannot be detected by any of the highly sophisticated methods that we have available today, it automatically means that the hazard — if any exists at all — is exceedingly small. Thus there is a great deal of time during which to study and analyse the problem without, in the meanwhile, putting appreciable numbers of people at serious risk

It is, however, this very inability to detect any deleterious effect in humans, accompanied by a reluctance to say that there is no effect at all, that constitutes our dilemma. How can one ever prove the negative case empirically? It is this question which is poorly understood not only by the general public, but by the many others who may be charged with the responsibility of protecting our health and safety. At present the only treatment of the question must rely heavily upon *judgement.*

THE PROPORTIONAL DOSE-EFFECT RELATIONSHIP

The ICRP and NCRP have long studied the possibility of somatic effects on the population from low doses of radiation delivered at a low dose rate. Of course, there have been no directly relevant clinical or animal data to work with because none existed Ref. [19]. Consequently, they *theorized* that if the effect of high doses and high dose rates appears to be proportional to the dose, the same relationship might be extended down to zero dose. If such a relationship might be applicable to low dose effects by implication, we would have to accept the position that for any dose, however small, there may be some effect, also however small. Furthermore, it would then be purely a *matter of judgement* as to where to set permissible dose standards That is precisely the situation into which we have worked ourselves during the past three decades

In the development of the linear, non-threshold dose-effect model, there were many reservations and explanations. But, if the linear, non-threshold relationship is accepted as fact, rather than as an assumption or model, one could presumably calculate the number of people who would be killed by any chosen level of radiation exposure. In spite of the fact that the acceptance of certain assumptions does not establish the reality of such calculations, some people continue to make them and hence contribute to the confusion of the public – and probably themselves. This puts a great burden upon a few knowledgeable groups or individuals to define some kind of a border line, however vague, between what is sense and what is nonsense in how far protection theories are put into practice *Judgement.*

ASSUMPTIONS INVOLVED IN THE PROPORTIONAL DOSE-EFFECT RELATIONSHIP

This is the situation which has led our several responsible protection bodies to postulate – as a base-line **for purposes of discussion, and to provide a sense of proportion** – the most conservative positions.

1. It is **assumed** that there is a linear dose-effect relationship for all radiation effects produced by doses in the range of several hundreds of rad down to zero dose.
2. It is **assumed** that there is no threshold of radiation dose above which an effect would occur and below which it would not.
3. It is **assumed** that all doses delivered to an organ are completely additive no matter at what rate they are delivered or what intervals there may be in the delivery.
4. It is **assumed** that there is no recovery from any effect of low doses of radiation.

It is known that none of these assumptions is strictly correct. The amount of deviation from them under some circumstances is known for a few limited situations. One of the most important areas of research ahead of us is to attempt some kind of evaluation of the nature and the extent of the deviations from these assumptions. The question is not whether there are deviations but how large are the deviations?

The difficulties inherent in answering this question perhaps make disagreement inevitable. It is all the more unfortunate then that unnecessary confusion has arisen as a result of arguments advanced recently. Some of these arguments have been less than useful for various reasons: they take assumptions and models as fact, leading to doubtful or incorrect conclusions; they ignore relevant data; they start from premises or theories that cannot be tested and therefore can be neither proved nor disproved. This situation does not make it any easier to arrive at judgements (which *must* be made in any case) and can lead to a climate of cynicism and mistrust.

A CONTINUED NEED FOR VALUE JUDGEMENT

Only a few of the problem areas that face us in the applications of radiation in medicine and industry have been mentioned. They will certainly grow in number and their solutions will be based in part on the technical findings of radiation effects on man at the low doses and low dose rates involved. But, as far ahead as we can see, they will be based even more on the *judgement* and wisdom of people. They will depend on moral attitudes towards possible injury to the worker on the one hand, and demonstrable safety and a "better life" to someone else on the other. They will involve important decisions of economics, and very often important political decisions.

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