Ethical Issues in Radiation Protection—The 1992 Sievert Lecture

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PREFACE

CONTRARY to those who have preceded me in this series of lectures, I never knew Professor Rolf M. Sievert because when he died in 1966, I was just starting my work in animal radiation biology and only later did I become acquainted with the subject and problems of radiation protection. However, judging from what I have come to know about Sievert through his work and conversations with friends who were associated with him, this large congress of people would not have been possible without his pioneering work. In him, scientific excellence was paralleled by penetrating intuition. In a 1947 lecture in honor of Sylvanus Thompson, commenting on the fact that a new epoch—that of atomic energy—was about to come, he had the following to say: "We cannot as yet estimate what risks of injury by radiation this epoch can bring. We have, however, reason to expect that the problem of protection against injuries by ionizing radiation will be of an entirely other magnitude that hitherto, and it is probable that it will become a general social problem of prime importance." Clearly, a remarkable foresight about a discipline that has gradually flourished internationally to its present state.

The honor that the International Radiation Protection Association (IRPA) has bestowed upon me by asking me to deliver this lecture is in sharp contrast with the little I have achieved in radiation protection. Others, with better credentials and authority, might have done a better job. But since this burden has fallen upon me, I can only hope that what I am about to say will not be too unworthy of the person we remember and of those who paid tribute to his memory in past lectures.

INTRODUCTION

My intention today is not that of delivering a sermon. It is simply to bring you to consider some of the ideas that underlie the principles and the numbers that we are confronted with every day in our profes-

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sional life. It is to discuss the fundamental values that are implicit in our practical activities, and to verify that we have not lost touch with the principles of human respect and compassion that must inspire our work as members of a scientific community.

Radiation protection is not a fundamental science, a free intellectual reconstruction of the why's and how's of nature, that may be regarded as intrinsically good, in so far as it only tends to enlarge the boundaries of human knowledge. Radiation protection is an applied discipline. Its purpose is to define the limits within which some human activities with potentially harmful consequences may safely be carried out. This requires discussion of the principles on which protection of the individuals and of the species should be based, and necessarily involves ethical considerations.

As some of you may know, ethical principles are of two kinds: there are the very general first-order ones, that is the values that should ultimately guide all choices for any action; and the more limited second-order principles, dealing mainly with the meaning and the applicability of the ethical language and the analysis of ethical concepts (Mackie 1977). Of the first set of principles, only one, perhaps, is required by radiation protection: the principle that to improve health and living conditions and thus to minimize the suffering of human beings is a good aim in itself, and therefore an objective that we ought to work for.

It is characteristic of ethical principles to be universalized, in the sense that when a principle is seen as ethically right, those who adopt the principle are committed to follow it under all relevant circumstances, irrespective of any qualitative differences of those stating, or affected by, the principle in question. A further stage in this process of universalization is to apply the principle irrespective of how individuals might vary in respect to their physical and mental qualities, resources, or social status, including those individuals that will only be borne in the future (Mackie 1977). Usually, radiation protection does not demand adoption of a third and more advanced stage of universalization, that of applying a principle irrespective of preferences, tastes, values, or ideas.

So, except for one very general first-order principle, radiation protection does not require any other major ethical statement. In this context, therefore, morality is understood in the restricted sense of a methodology to set special constraints of conduct in the interest of those exposed to radiation and to develop guidelines to restrain the selfish inclination by some agent or agents to act against such interest. This more limited function is, however, important in promoting the development of universally acceptable ethical behaviours.

Since radiation protection principles are meant to apply to all persons and societies, they should be sufficiently flexible to be adopted in countries with a wide spectrum of religious, political, social, and economic conditions; they also should be sufficiently comprehensive to apply reasonably to all activities involving radiation exposure, even those for which exposure has a low probability of occurrence. Finally, they should cover both present and foreseeable exposure situations.

Owing to all these requirements, it is obvious that such principles could not be derived from sets of values belonging to the cultural heritage of any particular group, but should be built on universally-shared secular values. They are, for example, the equality of rights for all human beings; the need to reasonably balance the interests of any individual against those of all others; the requirement to protect our species by preserving the material conditions for its continuation; and, finally, the right for each person to try to achieve freedom from one common heritage of the human condition, which is suffering and sorrow.

The main question I should like to discuss is: To what extent do we cover all these requirements in our particular field?

Present radiation protection doctrine (ICRP 1990) is based on a body of scientific knowledge, one underlying assumption and three general principles. My objective is to first discuss the adequacy of the existing scientific information for the purpose of setting safety standards; then to consider the foundations of the underlying assumption; and finally, to discuss a few aspects of the three general principles. All of this, of course, will be discussed in light of ethical considerations.

BASIC SCIENTIFIC DATA

Let me start with the scientific bases on which the system is built (Silini 1991). As you all know, we classify radiation effects into a few major groups, according to their nature and mode of expression at different dose levels. For some effects, our knowledge is derived from direct experience in man, gained in many cases in an attempt to cure disease, sometimes as a result of accidents in the course of industrial activities, and in a few cases as a consequence of deliberate acts of warfare or the development of weapons.

Broadly speaking, we identify at high doses deterministic effects on cells, tissues, or the whole body. These may be clinically dramatic but are usually not too difficult to avoid, except in the course of accidents. Experience of these effects in man is large. Therefore, their prediction as a function of dose, time, and radiation quality is rather well-founded (UNSCEAR 1977, 1986, 1988).

At low or very low doses, dose-rate effects of a different nature are seen. They are called late somatic (or stochastic) effects and consist in the appearance of an excess of cancer and leukaemia above the natural rate. Their existence is proven, but precise assessment of their rate of induction per unit dose is difficult in man. To this end, primary data obtained from human epidemiology must be adapted for general use to account for various dependencies on dose, dose rate, organs, age, time of induction, and other variables of

radiobiological interest. Recently, our understanding of all these risk-related variables has considerably increased. As a result, one feels that current estimates are more realistic than in the past and, perhaps, less likely to increase further, barring drastic changes in the projected trend of the primary data or new and unexpected findings. Of course, our knowledge of these effects is only descriptive. We still lack the understanding of the mechanisms through which cancer (and radiation-induced cancer in particular) is brought about.

For both classes of somatic effects—the deterministic and the stochastic—there is enough experience in man, so that models of induction in animals may simply be used to fill the gaps and to generalize dose–time relationships and trends with radiation quality. This is good because the species-specificity of many of these effects is so pronounced that it would simply be impossible to project rates of induction across species. It is acceptable, however, to use animal data in order to project general trends with dose and time or to validate mechanisms.

Unfortunately, for a third class of effects—the stochastic hereditary ones—we are still, to a large extent, dependent on data from experimental animals. The existence of clinically relevant hereditary effects brought about by the alteration of germinal cells in man has never been demonstrated, but the absence of such evidence is not in itself a cause for reassurance or concern. Since radiation may definitively cause such effects in many other living species and we know of no special reason why the human genome should be an exception, we must assume that the human species may also be susceptible. The best we can do, under these circumstances, is to take the estimates of hereditary effects in species that are phylogenetically near man and try to adapt these estimates for our species, on the basis of present knowledge of human genetics. Scientifically, this procedure is unsatisfactory. Ethically, it is justified out of necessity as the only possible course of action.

An important ethical issue deals with the assessment of those hereditary effects that may appear in man in the very far future. A significant step forward—at variance with previous (ICRP 1977) practice—has been taken recently by ascribing all genetic damage to the person exposed. This implies that all hereditary harm, be it the early-appearing dominant or the very long-term recessive damage, is treated in exactly the same way and given exactly the same weight. Provisionally, and until our capacity to quantify hereditary radiation effects will improve, this seems the most reasonable decision to make.

Equally unsatisfactory is our inability to account for the type of genetic disorders that are most relevant in man, the nonmendelian multi-factorial disorders. Thus, we must take note—with some disappointment—that the slight apparent reduction of radiation-induced hereditary risk estimates observed over the years is due both to a decrease in our confidence to quantify part of this damage, and to a real decrease of the overall estimates. Future progress as to the relative contribution of these two components is expected to depend critically on advancements in fundamental human genetics, rather than in radiation genetics (UNSCEAR 1986).

THE MAIN GENERAL ASSUMPTION

The main general assumption on which radiation protection rests is that, at sufficiently small doses and dose rates, there is a non-threshold linear relationship between the dose and the probability of induction of late somatic and genetic effects. I am purposely using the word assumption because this statement cannot be scientifically demonstrated at the low doses that would be required. In fact, the relatively low incidence (per unit dose) of radiation-induced cancer and hereditary diseases is masked by a very high background of other neoplastic and genetic conditions that are unrelated to radiation exposure in excess of the natural level. This happens for two reasons. One is biological because we have no means as yet of recognizing radiation-induced conditions from those that are caused by other agents. The second reason is statistical because it is impossible, at the low doses and with the small populations usually available, to demonstrate the significance of a small number of supposedly radiation-induced health effects over a large number of effects of the same kind of uncertain etiology.

The implications of the non-threshold linearity assumption are clear. It postulates, in essence, that each dose of radiation, however small, has a finite probability of producing effects of the stochastic type; and that each dose increment, however minute, will increase this probability in a manner that is directly proportional to the increment. The two aspects need separate discussion.

The first aspect has to do with the absence of the threshold. Radiation protection is among the very few health-protection disciplines to postulate the absence of threshold in the dose relationship for stochastic effects. In other fields of toxicology, one usually identifies a level of dose that carries positive evidence of harm, and then sets the "safe" limit well below that level. Such a procedure implicitly assumes that the dose-effect relationship has some threshold below which the toxic agent is considered harmless. By excluding a threshold, radiation protection not only adheres to a probabilistic approach to risk assessment, but also implicitly refuses to consider small risks as irrelevant. In fact, even if they are sufficiently low to be of no relevance for the individual, they might not be quite so irrelevant as source-related collective risks. This is the reason why both the individual and the collective aspects of the risk must be considered in any assessment.

Going now to the ethical implications of the linear relationship between dose and probability of effect,

there are justifications of a scientific nature for, and practical advantages in, this assumption.

Scientifically, we know that radiation energy is transferred to living matter along the tracks of ionizing particles. It seems reasonable to believe that, when the number of tracks per cell is on the average well below one (which happens at low doses and dose rates), single-track mechanisms giving rise to linear dose-effect relationships eventually must be the only ones operating, while double-track mechanisms (giving rise to quadratic relationships) must vanish. No matter to what extent linear relationships may be modified by various processes of repair of the initial damage, the kinetics will continue to be linear as long as the repair mechanisms will not themselves become dose-dependent, which only happens at very high doses and dose rates.

There are also practical considerations. On one hand, in the presence of a high background level of radiation, linearity of risk due to a small dose increment is not an unacceptable proposition. On the other hand, postulating any non-linear relationships would imply the need of keeping track of the radiation history of each person in order to calculate the attendant risk for each dose increment. Since radiation protection cannot clearly be tailored to each individual, the problem of assessing risks would have to be solved on the basis of large averages for and between individuals, which would be equivalent to assuming linearity from the start. Finally, dose-related assessments and restrictions would be difficult because the impact of each source would also depend on the exposure from other sources.

The question then is: If linearity between dose and the probability of stochastic effects is a scientific certainty or an inescapable practical necessity, where lies its ethical quality? It lies in the value assigned to the slope of the dose-linearity relationship, that is in the number we choose as the "nominal probability coefficient" for the planning of radiation protection. Obviously, this value should not be too low, otherwise the resulting radiation protection requirements would not be stringent enough. Nor should it be made artificially low by applying correction factors (for dose and dose rate, for example) under conditions where dose and dose-rate effects are not operating; such an approach would equally result in less stringent standards of protection.

It is less obvious that the nominal probability coefficient should not be too conservative, particularly in the face of the inherent uncertainties. However, excessive conservatism would unduly penalize practices involving radiation in comparative exercises against other practices carrying health risks. Excessive conservatism may also result in an uneven—and therefore inefficient—distribution of resources available for the protection against different sources of health risk. A realistic assessment of the coefficient is therefore to be advocated, in spite of the scientific and practical difficulties involved in such assessments. The best way to achieve this goal is through reasonably frequent reviews of the scientific evidence and the adjustment of the values as needed.

There are many ethical problems that could be discussed in connection with the assumption of non-threshold linearity. I will briefly touch on two.

The first problem concerns the existence of a variability in the appearance of stochastic damage among members of a population and the question for whom radiation protection standards should be developed. It is well established that susceptibility to cancer is not uniform, as shown by families with high predisposition to develop some tumor types. We also know that individuals homozygous for some genes are particularly sensitive to the immediate effects of radiation, and that cells *in vitro* that are homozygous or heterozygous for these genes are also more radiosensitive than cells from normal individuals. What we ignore is whether people susceptible with respect to "natural" tumor induction also may be more prone to develop radiation-induced tumors, and we have as yet no easy way to identify people with abnormally high sensitivity to radiation. Consequently, individual radiosusceptibility to cancer induction, and its distribution in the population, is an unexplored field.

Under these conditions, should radiation protection be planned with respect to the most sensitive or to the average member of the population? The answer is that probability coefficients for cancer induction are normally derived from people with all degrees of sensitivity. Thus, by using real epidemiological data as our reference point, we derive average values of population susceptibility, which include the most sensitive individuals. Such a procedure should be sufficient for planning protection, provided that the distribution of genes linked with hypersensitivity is not grossly different between different populations. It does not exclude, of course, that the occasional cases of known hypersensitivity could be dealt with individually in the context of occupational medicine.

The hypothesis of non-threshold linearity, among its many advantages, allows doses and probabilities of stochastic effects to be summed up in space and time. Integration in space I will consider later; here I am concerned (and this is my second question) with the assessment of radiation effects in time, i.e., with the potential damage to future generations and how protection should be planned for exposures taking place late (and sometimes very late) into the future.

The question has many facets. First, there is a general problem arising from the need of taking actions (or allowing actions to be taken) in the presence of uncertainties of a different kind about the long-term future. To cite just a few, think of the uncertainties inherent to the inadequacy of the human mind to foresee long-term phenomena, or the uncertainties about the behavior of any human group and the need to monitor the group's actions by independent evaluators. Other uncertainties arise in predicting the future of human societies and their degree of stability in the

face of changing ethical values, political organizations, social structure, and economic trends. Finally, how can we reliably forecast the future of our environment and the modifications caused upon it by present and future human behavior (Ethical Aspects on Nuclear Waste 1988)?

Then there is the question of our responsibilities to future generations and how to compare and value short-term effects with the very long-term damage resulting from present practices? Science is unable to suggest any answer to this kind of problem. Life is evolutionary by definition, and the balance between species is unstable over long periods of time. There are no obvious ethical concepts to be derived from evolution and its mechanisms. Solutions to these problems, therefore, must be sought at a different level. If it is true that all human beings are equal regardless of ethnic, religious, and national characteristics and that this right to equality could not be exercised without a right to a liveable environment, then there must be a principle of intergenerational equity by which we ought to respect the right of future generations by refraining from practices that may compromise their opportunities in the future. There is, in other words, an implicit social contract by which, since we derived from our ancestors our life and living means, we owe our followers the same heritage we received. We obviously cannot decide and plan for them, but we can at least avoid to preempt their future decisions by giving them the same opportunities we received (Shrader-Frechette 1981).

These statements are clearly too general to provide practical guidance. To translate principles into practice, radiation protection charges to the account of present practices the commitment of any future somatic harm. It also attributes to the account of any exposed person all the hereditary damage—dominant and recessive, monogenic and poligenic—estimated on the basis of doses received by that person. By doing so, it gives exactly the same weight to all types of harm caused by any exposure received, now or in the future, irrespective of the time at which such damage will become manifested.

THREE GENERAL PRINCIPLES

Going now to the main principles of the ICRP system of dose limitation, I would like to preface the discussion by pointing out that the system is to be taken in its entirety and that no one part (especially individual dose limitation) should be applied in isolation. One should also add what might appear redundant but, as the Latin sentence goes, "repetita iuvant": Just as it is necessary that the scientific data leading to practical recommendations be assessed in a fair manner, it is also imperative that implementation of the system be undertaken in good faith. Periodic evaluations of its effectiveness should help to improve performance and to achieve, together with a gradual lowering of the overall doses, a more even distribution of them in space and time.

Justification of a practice

In its most recent enunciation by the ICRP, the first general principle of radiation protection, that of justification of a practice, states: "No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes." At first sight, the principle appears utterly obvious: only a fool, in fact, could consider to undertake actions that are more harmful than beneficial. However, when closely examined, the statement appears very complex. Two concepts, benefit and detriment, are difficult to define and to apply to the other two terms, individuals and society.

The ethical problems posed by the interplay of these four terms are numerous. They turn, first of all, on how to define benefits in a comparable and consistent way and, above all, in a way which is fair to both individuals and groups. Second, who is to do this balancing operation and when? Third, how should one compare radiation-related benefits and detriments with benefits and detriments induced by other practices?

Before discussing ethics, let us first be clear on some points: There is no wish on the part of radiation protection experts to take any of these decisions. In democratic societies, the role of balancing quantities and values of a different nature, which are incommensurable by any rational standard, is left to people elected to exercise political authority. In stating this principle, radiation protection simply intends to put forward some requests. First, the radiation-induced health detriment specifically should be considered as one element in the decision process; second, the role of radiation protection specialists should not be that of choosing between a range of viable options, but that of advising about the viability of an option involving the use of radiation; and, third, judgments should not be made once and forever because options considered viable in a given context at a given time may not continue to be so with changing conditions or the passage of time.

In general, estimates of all the consequences of a decision, beyond the most immediate ones, are extremely complex because they interplay with the primary or secondary results of other decisions made independently by other agents. In practice, therefore, one simply assesses the ethical quality of the most immediate consequences of a proposed decision, leaving aside the obscure chain of second- and third-order events and their possible interplay.

Similar arguments apply to the complexities of the socioeconomic situations to be faced when making such decisions. Each individual belongs to different circles (family, group, workforce, nation, etc.) with different dimensions, aims, and requirements. Circles of different orders may cooperate or conflict with each other at any given time, and their interests also may change

with time. Given such a high degree of complexity, how could one possibly trace what may be satisfactory or detrimental for each actor in the game of life? An open mind, reasonableness, and a balanced judgment are prerequisites for fair decisions and these appear under such circumstances as the most valuable ethical requirements.

One often regards the principle of justification as a very extensive one, involving decisions at the national or international level in respect to large programs of action; these are certainly the most striking cases to which the principle applies. However, justification of generalized medical practices involving exposure to radiation is a process of the same nature; actually, the principle of justification should apply to any single medical practice. It is true that any doctor carries out this process almost implicitly. It is also true that in medical practice, benefits and risks accrue to the same patient, making decisions somewhat easier. Furthermore, the risks of not undertaking an examination are often more relevant than its potentially harmful consequences; i.e., medical practices are often heavily justified. But all these are simply secondary connotations of one and the same process of justification.

As a final note, it seems fair to ask that whoever has the responsibility of justifying a practice (from a clinician prescribing an x-ray examination, to a political body deciding on a nuclear program) should be well-informed of the values at issue and the responsibilities at stake for all active and passive subjects of that practice. Personally, I am not satisfied that this is always so, and I am sure that many of you have often felt the same way. This is exactly why there is a need for the apparently obvious principle of justification.

Optimization of protection

I will now turn to the second basic principle, the optimization of protection. In its newest formulation, this principle reads: "In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposure (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgments." The complications introduced into the new text are due to the deepening of the concept since the time it was first stated, to a novel attempt to enlarge it to include the so-called potential exposures, and to a desire to minimize the inequities in the resulting distribution of doses. All these, however important, are secondary technical specifications superimposed upon a general principle.

This stipulates that when attempting to minimize the doses received by individuals and groups, one comes to a point where further investments (of financial resources, staff, services, etc.) are grossly out of proportion with the doses saved. Since optimization is not performed in a vacuum but in a world with limited resources, at that point it is no longer advantageous to invest for increasingly small returns. I should hasten to state that this process of balancing doses and resources takes place under a ceiling of doses that should not be exceeded deliberately under normal circumstances. These are the individual dose limits that must be met irrespective of cost.

The optimization principle is obviously modelled on utilitarianism, a philosophical theory that takes human, general well being to be the foundation of morality. In its most extreme form, utilitarianism assumes that the right actions are those that cause the greatest happiness to the greatest number of people, happiness being defined as the balance of pleasure over pain. It further assumes that it is possible to measure and to algebraically sum pleasure and pain, and to take as the right action that which produces the least negative or the greatest positive balance (Engelhardt 1986).

To philosophers, the main merits of utilitarianism are its coherence and unselfishness that provide a unitary procedure for morally correct decisions. But there are also objections; for example, is it really possible to quantify all the values to be balanced? Is the greatest total happiness the goal to be pursued or is the distribution of happiness also an important factor? For these and other reasons, utilitarianism is not universally accepted as a true ethical system (Mackie 1977).

To be sure, radiation protection adopts and recommends the concepts of the theory in a restricted sense, starting from the main premises. For example, human well being is given the more limited meaning of absence of effects on health. Radiation protection borrows the ideas of the theory simply as a device to counteract selfish interests on the part of individuals and groups against other individuals and groups. In other words, it uses its main principles as a methodology to help setting boundaries to the pursuit of narrow egoistic tendencies.

It is interesting to point out that the utilitarian theory, which is based on a purely aggregative principle, does not itself provide any precise answer regarding boundaries. The main criticism about the theory is actually that it is open to the possibility that the happiness of some may be reached through the misery of others. To avoid such a danger, a distributive principle must be added to the aggregative rule of the theory, to limit the unfairness (or at least the most extreme unfairness) in the sacrifice of some for the sake of others. So much for the ethical foundations of utilitarianism.

Discussions on optimization must start from its objective, which is that of limiting exposure and thus decreasing the associated health detriment. If disease and suffering have the same value, irrespective of their etiological agent, it appears intuitively preferable to make the most out of the resources available. There is

no apparent reason why, for the same amount of human detriment avoided, one should invest more resources to reduce radiation damage, while, for example, neglecting the prophylaxis of some infective disease through vaccination, or the reduction of transportation accidents by an efficient communication system, or the cure of cardiovascular emergencies by increasing the number of intensive care units over the territory. All these are aspects of a well-integrated system of health planning and should be looked at and cared for in a uniform manner to achieve a distribution of resources that avoids a maximum of detriment and suffering.

To help achieve optimization, a variety of formal decision-making techniques may be used. One of these, the cost-benefit analysis, requires that the two quantities to be weighted against each other should be expressed in the same units, usually monetary units (ICRP 1983). This need has often given rise to the misunderstanding that expressing a health risk in terms of money is equivalent to assigning a value to human health, which is definitely a highly unethical and therefore unacceptable procedure. It is easy to rebut such a critique on a number of accounts. Semantic reasons first: The amount of money conventionally attributed to life is not the cost of life but the resources needed to save that life. Second, conceptual reasons: Cost-benefit analysis is simply a technique used to save the maximum amount of life and suffering. Third, procedural reasons: Optimization is carried out on a statistical basis for the sole purpose of programming the least possible exposure. A procedure of analysis *a priori* is quite different from situations encountered in medical practice, where no efforts should reasonably be spared to take the best possible care of a disease that has actually occurred. Thus, I have personally no difficulty in accepting the principle of optimization as morally sound.

Formal methods of optimization have many advantages. To cite the principal ones, they make comparisons systematic and quantitative and require decisions to be taken in a sequence of steps that anybody at any time could trace and check. The main disadvantage is that it may be difficult—perhaps impossible—to assign meaningful quantitative weight to some "intangible" values that could, as a result, be neglected (Reich 1978).

However, no decision process is entirely free from value judgments. How is one to unambiguously separate facts and opinions, descriptions and evaluations, when the appraisal of those who perform an analysis may to some extent determine its outcome? This difficulty may become crucial in assessing the uncertainties on the results of the analysis. Some, for example, will take a very low probability of risk as evidence that no injury will in fact be seen; on the contrary, the logical impossibility to prove absence of injury will strengthen in others the belief that injury will eventually result.

In my mind, the advantages of formalized techniques of optimization overcome by far the critiques that can be raised against them. In most of the examples that I know of, the results appear unambiguous. In cases of doubt, the old hippocratic rule "primum non nocere" should take priority over an uncertain benefit.

Yet, many individuals have difficulties in accepting and applying optimization. They prefer to rely on compliance with limits, thus adopting a view of protection that falls short of its real spirit. Some managers are eager to increase their economic returns; some regulatory agencies are inclined to assert their authority rather than to educate the users to a correct culture of safety; and some inspectors are keen to set rules against which to define statutory offenses. All these tend to encourage such erroneous concepts and behaviors.

We should remember instead that there is no definite boundary between safe and dangerous doses; that working at the limit for a long time produces a risk which is definitely bordering on unacceptability; that below the limits there is a wide region of doses that can be kept as low as reasonably achievable. In the recognition and implementation of these principles lies exactly our professional responsibility. To verify compliance with limits does not require any great ability; it is infinitely more challenging and rewarding to improve on existing exposure situations.

This leads me to a further ethical point to which little attention is paid: The concept and practice of optimization confers a dynamic character to the objectives of our profession, which is totally at variance with the static concept associated with limit compliance. Needless to say, the former is much more valuable since it leads to an ever-increasing standard of performance.

Individual dose limitation

The principles of justification and optimization may to a large extent be viewed as logical steps in the strategy of decisions applicable to many human activities (ICRP 1989). With the third principle, that of individual dose limitation, we enter a field that is very specific to radiation protection and could not be implemented without detailed notions of radiation effects and risks.

When discussing the intrinsic limitations of utilitarianism, I have already mentioned that in order for it to be implemented, the theory requires that a distributive principle be added to the aggregative principle to avoid major inequities. Recognizing such a need, the new recommendations of ICRP suggest the use of source-related restrictions to individual doses, called dose constraints. They are meant to avoid a very uneven distribution of doses in the process of optimization. But these constraints are applied usually well below the individual-related primary limits of exposure, which I would like to discuss now. I shall do so by tracing the logics in their derivation.

Regarding the exposure of workers, the ICRP has adopted in the past the policy that it did not wish to see radiation risks higher than risks of accidental death in other safe industries (ICRP 1977). At that time, the risk of death was the yardstick for comparing the

ground that death from cancer (or any comparable hereditary effect) was the worst possible consequence of radiation exposure: If radiation could be shown to be safe on this ground, other comparisons based on non-lethal consequences would be even safer.

Recently, however, new considerations have been pointed out. First, the safety of industrial operations is found to be at different levels in countries with differing conditions of socioeconomic development. Second, in any one country, the rate of accidental death in various industries tends to decrease with time due to an ever-increasing demand for safety. Third, the risk of death in industrial activities is calculated by averaging over groups of workers, while radiation dose limits are meant to apply to individuals. Fourth, non-fatal harm should be added to the risk of death for the purpose of setting limits. And, finally, in deriving previous limits, assumptions have been made regarding their implementation, while, in principle, limits should be set independently of any assumption about their eventual compliance.

New scientific evidence has also shown that age at irradiation and time since exposure are very important features in the induction and expression of radiation-induced death due to cancer or hereditary damage. The preamble to old wills in my country used to say that "nothing is as sure as death and nothing is less sure than the time of its occurrence." In other words, after a few centuries, we also have come to realize that, since the probability of death is 100% for all of us, it is hardly a good means of comparison. On the contrary, it is the age at which death occurs (together with the quality of life afforded by the non-lethal conditions, I should add now) the variable that matters.

At the same time, it has been pointed out that probably the most correct way to project the occurrence of radiation-induced cancer into the future from present epidemiological data is through a multiplicative model in which the natural rate of induction and the radiation dose together determine the final outcome of a given exposure. (An additive model had been used until now.)

All these considerations and facts prompted the ICRP to adopt a different course of action in the selection of the limits. The Commission proposes now to enlarge the perspective of the exercise and to consider a wide range of attributes associated with radiation-induced effects (neoplastic lethal and non-lethal and severe hereditary conditions). These attributes are: the probability of death from effects over the entire life; the lifetime lost when radiation-induced death occurs; the combination of both these parameters, that is, the reduction of life expectancy; the annual distribution of the attributable probability of deaths; and the increase in the probability of dying in each one year at any age, conditional upon having reached that age. Then the Commission calculates the value of the attributes at doses of between 10 and 50 mSv y^{-1} (corresponding approximately to 0.5–2.5 Sv in a working lifetime) and selects as the limit the annual dose that it considers just short of unacceptable.

There is obviously a degree of subjectivity in selecting such a value, but hopefully not a great amount of arbitrariness. It is important to spend one minute to illustrate the main points of the reasoning.

First of all, why set the limit at the level that is just unacceptable and not at one that is clearly acceptable? Because under the assumption of linearity without threshold the only dose acceptable without question is zero. This alternative would, therefore, reject all doses from man-made radiation and also would be meaningless in view of the high level of unavoidable natural radiation. On the other hand, setting the limit at a dose just short of unacceptable carries the corollary that to keep a worker continuously at the limit implies a risk which is definitely too high.

Second, new scientific evidence and its reinterpretation has shown that the nominal risk coefficient for tumors and genetic effects combined had increased since 1977. On the basis of the previous limit and of the new nominal risk coefficients, a worker continuously exposed at the limit would see his life expectancy reduced by about 1 y with an attributable probability of death of about 9%. These figures universally would have been regarded as unacceptable and the limit should have been decreased. The question is: by how much?

To use the words of the Commission, the new limit should be such "that the total effective dose received in a full working life would be prevented from exceeding about 1 Sv received moderately uniformly year by year and that the application of its system of radiological protection should be such that this figure would only rarely be approached." On this basis, "the Commission now recommends a limit on effective dose of 20 mSv per year, averaged over 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year" (ICRP 1990).

I would be lying to you if I would claim that this decision was an easy one to make. It was a compromise just short of unacceptable to any of those who had to take it and came to be judged as tolerable for the Commission as whole, with various shades of dissatisfaction. But this is inevitable. As I said before, when deciding on these matters each person carries his own human, cultural, and professional sensitivities which add to the logical line of thought (and I specifically mean "adding" in the sense of enriching). My own tendency would have been more restrictive, and therefore I have to remind myself all the time that limits are recommended for universal use and should cut across the needs of various groups and societies. They are suggested values that individual countries may accept or reject, hopefully to adopt lower limits. Actually, the system itself recommends various ways to reduce the risk implied by the primary limits.

As to the limit of dose for the public, the ICRP proceeds in analogy with that for workers. It still aims

at a dose level just short of unacceptable for continuous exposure and it still assesses the limit by comparing various attributes of lethal, nonlethal, and hereditary harm. It comes eventually to a recommended level of 1 mSv y^{-1}. An alternative procedure, that of selecting a fraction of the natural background to be the limit, would have been unacceptable in principle because the fact that we are exposed to doses from natural radiation sources (even with ample fluctuations in space and time) cannot in principle justify the addition of any dose, however small, from man-made sources. Comparisons with background are useful *a posteriori* but would be unwarranted *a priori* for the purpose of selecting limits.

The choice for the public of a limit that is considerably smaller than for the workers (about a factor of 20, at present) is ethically justified on the grounds that this limit applies to a much larger population, that exposure is for the whole life (and not only for the working life), and that the public at large also includes here the most susceptible young ages. Also, members of the public are only protected by source control and not by individual monitoring. All these considerations make sense from a general point of view.

What is more perplexing to me is why workers should in theory be allowed (as they in practice do) to receive higher doses than other members of the public of the same age. Explanations usually given are that workers are paid to do a given job, but my objection is that this implies acceptance of the concept that a potential risk to human health and life may be traded for money. It is also said that workers undergo the relevant risks voluntarily as a matter of free choice. But is this true under conditions of high unemployment? And, in any case, is it fair to ask anybody to choose between no work and work under high risk?

The fact does remain that limits for professional exposure are normally higher than for public exposure for many human activities. I have no argument to oppose the wide public acceptance of this state of affairs. It could be an excess of scruples on my part, and it could be utopian and unrealistic even to contemplate such an idea. I would eventually like to see a system in which each person is protected as a human being, irrespective of any working condition, and I believe that on this point there is room for further improvement.

CONCLUSIONS

At the end of this presentation, I should try to answer the question that has long been in my mind and perhaps in your mind too. Is the present system of radiation protection founded on sound ethical grounds? Overall, I believe that the answer should be "yes" because the ethical propositions on which it is founded are good; the methodologies to develop the basic principles into a set of recommendations are morally acceptable; and the system appears reasonably coherent, flexible, and stringent enough to keep the risks low but not zero, which would be an impossible target to achieve as long as there are benefits to be gained from the use of radiation.

Naturally, as is true of all human endeavors, the system still could be improved. Some improvements will come about in due course as new experience is gained. This applies, for example, to the updating of risk estimates based on new scientific evidence. From it, as in the past, the revision of the present recommendations will probably occur.

Other improvements will presumably require original research and development in order, for example, to further clarify the meaning of the principle of justification, or to include environmental, in addition to human, protection.

To meet further and more advanced requests, revolutionary, rather than evolutionary, approaches of the present system might be necessary. I am referring here to my suggestion to protect individuals as human beings and not as workers and the public, or to the further universalization of the basic ethical principles to take into account non-objective health detriment and other preferences, desires, or ideals.

Such further developments would almost certainly make the system more stringent. As it becomes so, some people may find it more acceptable but others may look upon it as being too obtrusive. We certainly should ask ourselves whether we have taken the present system as far as it could go in order to preserve coherence, which is undoubtely its main merit. On the other hand, we must see that protection against radiation is not pushed too much because it may fall out of perspective and may be unfairly penalized in comparison with protection against other health hazards.

My personal feeling at present, from a global perspective, is that adoption of the system, imperfect though it may be, by all countries would be likely to save more doses than might be saved by further marginal improvements in countries where the system is already well in operation. If this feeling is correct, then we should continue working, as we have done in the past, in order to develop the system rationally while trying all of the time to behave reasonably.

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