IRPA - International Radiation Protection Association

11th IRPA International Congress; Madrid, Spain - May 23-28, 2004

The Sievert Lecture

Protecting Life against the Detrimental Effects Attributable to Radiation Exposure:

Towards a Globally Harmonized Radiation Protection Regime

Abel J. González

Wagramerstraβe 5, (A-1400) Vienna, Austria; abel_j_gonzalez@yahoo.com

PURPOSE AND CONTENT

It is a distinct privilege to present my Sievert Lecture in Spain. Around a century ago, my paternal grandfather emigrated from his lovely Galicia, in the extreme northwest of this beautiful country, heading for the promised land offered by my home country, Argentina. I am sure that from somewhere in our infinite universe he is proudly witnessing his grandchild returning to the motherland. I am grateful to IRPA and to the IRPA Societies, in particular to the Sociedad Argentina de Radiproteción and to the Sociedad Española de Protección Radiológica, for the honour of becoming another Sievert Lecturer.

I am presenting this Sievert Lecture *in memoriam* of Dan Jacobo Beninson, my mentor and friend, one of the great contributors to the sciences of radiation protection, who was predecessor as the Sievert Lecturer at the 9th Congress of IRPA, in Vienna, in 1996 [Beninson, 1996].

The Lecture will address the sciences associated with the protection against the detrimental effects attributable to radiation exposure, including the debates surrounding them and the contests they trigger. The ultimate aim of the Lecture is to promote a navigation path towards a globally harmonized radiation protection regime.

The Lecture is divided in five parts, as follows:

- The first part will summarily refer to the outcomes, methods, validity, scope and limitation of the current knowledge about the health effects attributable to radiation exposure, namely to the ***epistemology*** of the sciences that provide the basis for radiation protection.
- The second part will recapitulate the current international radiation protection ***paradigm***, namely the global conceptual model for keeping people safe from radiation exposure.
- The third part will address current ***controversies***, namely disagreements among experts on a number of issues related to that epistemology and paradigm.
- The fourth part will refer to current ***challenges***, namely calls and appeals to prove or justify our current approaches to radiation protection.
- Finally, the fifth and last part will submit proposal for ***navigation***, namely suggestions for processes and activities aimed at directing the course of radiation protection in the future.

Please be tolerant of such a long allocution! I will not be offended if you doze but hopefully you might try to avoid snoring.

I ought to warn the audience that I have to include some mathematics in my presentation, a move that is usually seen with apprehension by many practitioners in radiation protection. I would like to emphasize that my intention is just to profit from the international language provided by mathematics, which is a real *lingua franca* and an important tool for common understanding in international gatherings such as the IRPA Congresses. A good byproduct of using mathematics in discipline as argumentative as radiation protection is that mathematics leaves no room for argument.

EPISTEMOLOGY

The epistemology of the radiological sciences is presented hereinafter, under the quote that "*there is not a single rule, however plausible, and however firmly grounded in epistemology, that is not violated at some time*…" [Feyerabend, 1975]. The rules to be eventually explored are those related to provability that radiation health effects could retrospectively be attributed to incurred radiation doses, and to the prospective probability that planned radiation doses could cause radiation harm. These fundamental rules are sometimes confused, *inter alia* because provability and probability are paronyms, words derived from the same root, but not synonyms, as they denote fundamentally different meanings.

Knowledge on radiation health effects is provided throughout various scientific paths, including:

- clinical and pathological diagnosis of radiation harm suffered by people exposed to radiation;
- epidemiological estimates of increased incidence of radiation-associated health effects in exposed population groups;
- experimentation with exposed animals; and
- understanding of the radiation effects on cells, mainly through research on cellular and molecular biology.

Knowledge will eventually be condensed as informed judgments that are somehow subjective but based on logical models enriched by objective estimates resulting from those paths. **It is essential to recognize that there are epistemological limitations to such knowledge**!

The biological effects of radiation exposure

The models describing the interaction of ionizing radiation with biological matter and its effects has been studied and described over years by the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) (see the latest UNSCEAR reports on the subject, [UNSCEAR 2000 and 2001]. UNSCEAR has provided the international estimates of the health effects of radiation exposure and what has been termed an international accord on this controversial subject [González, 2004].

The basic element of the current consensus is that radiation may interact with the deoxyribonucleic acid (DNA)[1] that is packed into chromosomes located in the nucleus of cells, either directly on the DNA components or indirectly by producing oxidizing agents in their surroundings. As a result of such interactions, the information encoded in the DNA structure can change resulting in a variant form –a process termed *mutation*.

The logical sequence of the phenomenon is straightforward. When cells are exposed to radiation the options are that radiation does interact with DNA or that it traverses the region without interaction. If radiation does interact, the options are that such interaction does trigger DNA mutations or does not. If mutations do occur, the alternative outcome options are that mutations are repaired without errors throughout the

[1] DNA is a long macromolecule is medium that transfers genetic characteristics. It is composed of two nucleotide strands coiled around each other in a ladder-like arrangement with the sidepieces composed of alternating phosphate and deoxyribose units and the rungs composed of the purine and pyrimidine bases, adenine, guanine, cytosine, and thymine. The genetic information of DNA is encoded in the sequence of the bases and is transcribed as the strands unwind and replicate.

sophisticated and efficient cellular system of repair using a battery of *ad hoc* enzymes[2], or that mutations are either wrongly mended or no repaired at all. In the latter case the ultimate alternative outcome options are that:

- either the cell cannot survive the mutation, and becomes an unviable cell and die; or,
- the cell survives, becoming a viable cell that contains mutated genetic information.

This process may occur in both, somatic cells and germ cells. In the first case, the process could result in harm to the person exposed to radiation; in the second case, it could transmit harm to the descendants of the exposed person.

Following a simple interaction model, it is straightforward that the probability of interaction (and eventually of mutation), p_D, following radiation exposure at dose, D, is:

$$p_D = (a\,D + b\,D^2 + \ldots k_n\,D^n)\,e^{-cD},$$

where:
a, b,…n.. are constants,
the terms $k_n\,D^n$ represent multiple n interaction, and
the term e^{-cD} expresses the diminution with dose of the number of target cell due to the process of cell killing.

The terms with power >2 are trivial and p_D becomes:

$$p_D = (a\,D + b\,D^2)\,e^{-cD}$$

an expression that is usually termed 'linear quadratic relationship'.

At low dose rates the frequency of interaction is extremely low (for instance for gamma rays with a typical energy of around 1MeV, a dose rate of around 1mSv/year will result in around 1 interaction per year per cell. Therefore, at such low dose rates, the terms $b\,D^2$ and e^{-cD} can be ignored, and p_D becomes

$$p_D = a\,D$$

which is the expression confusedly termed, 'linear non-threshold', LNT, dose response at low doses.

Deterministic effects

A possible outcome of radiation exposure of living matter is the killing of cells. If few cells die, e.g., as a result of exposure to relatively low doses, the health outcome is usually not serious, because the cell will normally be replaced, and tissue reactions will not occur. However, if the dose is high, resulting in a large number of killed cells, then tissue reactions can appear. Serious tissue reactions may lead to blisters, scalds, burns, tissue injuries, organ failures, and eventually death. The ultimate health effects resulting from this process

[2] The cellular repair of DNA mutation is extremely effective. The enzyme glycosylases recognize the lesion and releases damaged base, the AP-endunuclease makes an incision and releases remaining sugar, the DNA-polymerase fills the resulting gap but a nick remains and the DNA ligase seals the nick completing the repair. This efficient mending system is however not error free. In particular, if the damage is clastogenic error-free repair is unlikely, namely if damage includes disruption or breakages of chromosomes, leading to sections of the chromosome being deleted, added, or rearranged a permanent damage will probably remain.

are qualified as '***deterministic***' because, if the dose is above a threshold value, the manifestation of the effects is determined to occur. Deterministic effects, therefore, are manifested as the result of injury in populations of cells. Naturally, the severity of the deterministic effects augment as the dose is increased. The probability of this effects occurring with dose should follow a logistic function (i.e., a sigmoid curve of 'S' shape) of dose, which is characterized by a *de facto* threshold dose because the function is stepped for most effects.

Deterministic effects are individually diagnosable throughout radio-pathology techniques and modifiable by post-irradiation medical treatment and procedures such as the use of biological response modifiers. The International Commission on Radiological Protection (ICRP) [ICRP, 19991] has summarized described deterministic effects as follows: *Deterministic effects result from the killing of cells which, if the dose is large enough, causes sufficient cell loss to impair the function of the tissue. The probability of causing such harm will be zero at small doses, but above some level of dose (the threshold for clinical effect) the probability will increase steeply to unity (100%). Above the threshold, the severity of the harm will increase with dose. Thresholds for these effects are often at doses of a few Gy or dose rates of a fraction of a Gy per year*.

Stochastic effects

Another possible outcome of the cellular irradiation is that the cell remains a viable but mutated cell. The DNA of a mutated cell would encode different amino-acids and produce changed proteins. The mutated cell will therefore behave differently than a normal cell. Depending on the place in the DNA sequence where the mutation has occurred, the cell behaviour could become detrimental for the organism. For instance, if tumour-related genes of a somatic cell are mutated, the mutated cell could become the original source of a malignancy[3]. If the mutation occurs in a germ cell, it can be the origin of a heritable effect. The process is aleatory, depending on chance and occurring at random, and therefore the manifestations of such mutations are qualified as '***stochastic***'. In sum, stochastic effects of radiation can be malignant diseases and heritable effects; for these effects the probability of an effect occurring, but not its severity, is regarded as a function of dose without a dose-threshold.

Increases in the incidence of stochastic effects can be estimated in exposed populations throughout epidemiological studies but they cannot be discerned in individuals because the radiation effects do not differ from the same effects caused by other reasons. The ICRP [ICRP, 1991] has summarized the stochastic health effects as follows: *Stochastic effects may result when an irradiated cell is modified rather than killed. Modified somatic cells may subsequently, after a prolonged delay, develop into a cancer. There are repair and defence mechanisms that make this a very improbable outcome. Nevertheless, the probability of a cancer resulting from radiation increases with increments of dose, probably with no threshold. The severity of the cancer is not affected by the dose. If the damage occurs in a cell whose function is to transmit genetic information to later generations, any resulting effects, which may be of many different kinds and severity, are expressed in the progeny of the exposed person. This type of stochastic effect is called "hereditary"*.

The prevalent opinion on the stochastic process leading to radiation-induced malignancies is that: radiation randomly mutates DNA; there is a random failure to repair the DNA mutation; the cell may survive and become a viable but mutated cell with changes in the carcinogens; as a result a tumour may be generated and eventually promoted; somehow a malignant conversion may occurs; and, a metastasis of the malignancy would eventually follow.

Epidemiology

[3] Mutations associated with malignancies may occur in proto-oncogenes, tumour suppressor genes, repair genes and genes triggering cell death.

Estimates for the probability of manifestation of stochastic effects are performed through epidemiology, that branch of medicine concerned with the incidence and distribution of diseases and other factors relating to health. A relevant epidemiological study is that of the survivors of the nuclear bombing of Hiroshima and Nagasaki in Japan (this study is usually known as the *life span study* or LSS). The LSS cohort encompasses 86,611 survivors of both sexes and all ages with dosimetric data over a range of doses. According to recent data, after 47 years of follow-up (1950-1997) [Preston et all, 2003]: 45 per cent of the cohort were still alive; of 10,127 deaths from solid cancer due to all causes, 479 would be estimated to be associated with the radiation exposure from the bomb detonations, as would 93 leukaemia deaths out of 296 leukaemia deaths from all causes. Thus, the LSS solid cancer mortality could be summarized as follows: around 5% of the total cancer deaths could be attributable to radiation, such difference corresponds to a standard deviation, σ, of 3.7, namely is just above the limit of statistical discern, which I usually taken to be for a σ around 2.

A succinct description of the epidemiological estimates of malignancy risks can be summarized as follows: Following exposure to 1000 mSv of acute dose, the mortality risk in the exposed population is around 0.9% for leukæmia and around 11% for solid cancers (around 9% for men and around 13% for women). Two models of cancer projection are used for the estimates; the additive model[4] for which the mortality risk for feminine solid cancers is around 8% and the more conservative (and most used) multiplicative model[5] for which such risk is the reported value of around 13%.

No epidemiological estimates are available for low dose and low-dose rate exposure situations. These estimates are at the moment within epistemological limitations of epidemiology. Therefore, since the effectiveness of radiation is judged to be lower at low dose and dose-rate, for low dose exposures the estimates of risk at high doses are reduced by a 'dose and dose-rate effectiveness factor' (DDREF), which is a judged factor that generalizes the usually lower biological effectiveness (per unit of dose) of radiation exposures at low doses and low dose rates as compared with exposures at high doses and high dose rates. The value of DDREF is estimated to be around 2. Therefore, with a DDRF=2 and depending on the projection model, the risk of malignancies at low-dose exposure situations is subjectively estimated to be around 0.004 % to around 0.006% per mSv, i.e. approximately around 0.005% per mSv.

While hereditable effects have not been observed in human populations, it is assumed from extrapolations from animal studies that for a human population exposed to radiation in one generation, the risk of hereditable effects to the progeny of the first post-radiation generation should be around 3000–4700 cases per Gy per one million progeny, In sum, for hereditable effects, it could be inferred that the total risk to first generation following parental exposure might be subjectively estimated to be around 0.0003 - 0.0005% per mSv, namely around 1/10 of the risk of fatal carcinogenesis, constituting 0.4-0.6% of the baseline risk.[6]

[4] The additive model is a time-constant absolute risk projection model, which assumes that, after some latent period, the annual excess cancer risk is constant. This additive model results in the cancer rate following exposure to a dose of radiation being given by the baseline cancer hazard function in the absence of exposure to radiation, i.e. the underlying cancer rate at a given age and for a given sex, plus the function describing the dose dependency of the cancer risk, which is often taken to be the linear–quadratic $aD + bD^2$.

[5] The multiplicative model is a time-constant relative risk projection model, which assumes that, after some latent period following an exposure to radiation, the annual cancer rate rises in a manner proportional to the underlying annual cancer risk. This model results in the cancer rate following exposure to a dose of radiation being given by the baseline cancer hazard function in the absence of exposure to radiation plus the function describing the dose dependency of the cancer risk but multiplied by that baseline cancer hazard function.

[6] Taking into account available radio-biological information and epidemiological studies in animals, UNSCEAR had made extrapolations of excess heritable diseases in one generation due to low-dose exposure [UNSCEAR, 2001]. UNSCEAR concluded that the excess in first generation is: for dominant effects (including X-lined diseases) ~750–1500 per million per Gy vis-à-vis a baseline

Antenatal effects are those health effects of exposure incurred before birth that will express either before birth, on the conceptus, embryo, or foetus, or after birth, in the child or the adult, or in his or her descendants. The ICRP has noted that antenatal exposure should not be a specific protection case in prolonged exposure situations where the prolonged annual dose is well below about 100 mSv; in fact, there is a *de facto* threshold for antenatal effects of around 100 mSv. Notwithstanding, it has been observed antenatal effects in epidemiological studies of children from survivors of the bombing of Hiroshima and Nagasaki, who were exposed in utero during the 8-15 weeks of pregnancy. These children have a risk of a shift in the intelligence quotient, IQ (the score derived standardized tests designed to assess human intelligence) of around 30 IQ units per 1000 mSv of exposure. The change in the IQ of an individual that can be caused by a dose of about 100 mSv will be no more than 3 IQ points; mall shifts in IQ cannot be clinically identified. All the observations on IQ relate to high doses and high dose rates [ICRP, 1999, 2003].

Summary

In a simplified summary conclusion, the detrimental effects associated with radiation exposure can, for radiation protection purposes, be briefly described as follows:

- At high levels of radiation doses, the cell-killing properties of radiation exposure will cause "deterministic" effects, i.e., health effects that are determined to occur above certain dose thresholds, with their severity increasing with dose, which can be clinically diagnosed in the individual exposed; the probability of death from these effects approaching unity for whole body doses of around few Gray.

- At any dose level, radiation exposure may increase the inferable risk of induction of "stochastic" effects, i.e., health effects such as malignancies and hereditary diseases, which background incidence is relatively large. The increase is proportional to the radiation dose incurred as follows: around 0.005% mSv for cancer and below around 0.0005% mSv for hereditary effects. It should be noted, however, that these estimates are associated with unavoidable uncertainties. The processes occurring from the ionization of living matter by radiation exposure up to the expression of the attributable detrimental health effects are extremely complicated and can only be assessed with considerable uncertainties. For stochastic effects they extend over different time periods: the physical interaction taking place in millionths of microseconds, the physiochemical interactions occurring in thousandths of microseconds up to milliseconds, the biological response arising in seconds up to days, and the stochastic medical effects expressed after years, decades and—in the case of hereditary effects probably centuries.

- Antenatal effects may occur if the embryo or foetus receive doses higher that ~100mSv.

As it will be seen hereinafter, these estimated prospective inferences of risks do not automatically mean that radiation effects can be attributed retrospectively to radiation doses, particularly at low radiation levels. As indicated before there are epistemological limitations in our understanding of radiation effects, which are sometimes ignored. UNSCEAR confronts a serious challenge in this regard. In particular, the attributability of radiation effects at radiation exposure situations delivering low doses is an open issue. The prospective inference of risk for planned exposures at low doses is also a challenge but ICRP is already talking the issue and a publication on Low-dose Extrapolation of Radiation-related Cancer Risk will be issued soon.

PARADIGM

---

frequency of 16,500 per million; for chronic multi-factorial diseases ~250–1200 per million per Gy vis-à-vis a baseline frequency of 650,000 per million; and, for congenital abnormalities ~2000 per million per Gy vis-à-vis a baseline frequency of 60,000 per million (chromosomal effects were assumed to be subsumed in part under the risk of autosomal dominant and X-linked diseases and in part under that of congenital abnormalities).

The radiation protection paradigm is presented hereinafter under the quote that '*in paradigm choice there is no standard higher than the assent of the relevant community*' [Kuhn, 1960].

The current paradigm is based on the recommendations of ICRP (see the latest recommendations in [ICRP, 1991]. These recommendations are used worldwide in national and international radiation protection standards. It should be noted however that at the time of this Lecture ICRP is considering a substantial change on its recommendations, and in particular in its approach to the protection to emergency and extant exposure situations [Clarke, 2004; Holm, 2004].

The fundamental bases of the paradigm are the estimated risks of radiation health effects that can be prospectively inferred for radiation exposure situations and the associated expectation of harm. The level of natural background doses that people unavoidably incur is sometimes used as a reference, yardstick and benchmark.

The ultimate purpose of the paradigm is to prevent the occurrence of deterministic effects and to limit the prospective harm of stochastic effects. If doses are kept below the threshold of deterministic effects, their occurrence could be avoided. The estimates of prospective risks of stochastic effects were discussed heretofore and the ICRP uses these estimates to limit the potential *detriment* (or expectation of harm)[7] from stochastic effects. The values of the detriment at low dose for both a working population and a general population are currently estimated by ICRP to be as follows [ICRP, 1991]: for fatal cancer in adult workers, 4.0 10^{-2} Sv^{-1} and in a whole population 5.0 10^{-2} Sv^{-1}; for non-fatal cancers effects in adult workers, 0.8 10^{-2} Sv^{-1} and in a whole population 1.0 10^{-2} Sv^{-1}; for severe hereditary effects, in adult workers 0.8 10^{-2} Sv^{-1} and in a whole population 1.3 10^{-2} Sv^{-1}; resulting in a total detriment of 5.6 10^{-2} Sv^{-1} in adult workers and in 7.3 10^{-2} Sv^{-1} in a whole population.

The perspective given by the ubiquitous presence of natural background radiation can be summarized as follows: practically nobody incurs doses lower than around 1 mSv/year; the majority of people around the world incur an average of 2.4 mSv/year, many people, in many areas, incur a typically high value of around 10 mSv/year; and, few people y few areas my incur high values of around 100 mSv/year [UNSCEAR, 2000].

Taking into account the basis and purpose described above, the ICRP has recommended [ICRP, 1991] the conceptual paradigm of radiological protection that is used worldwide and has historically provided the basis of the international radiation protection standards [IAEA, 1960, 1962, 1967, 1978, 1982, 1996b]. The main objective is that a system of radiological protection should aim to do more good than harm, should call for protection arrangements that maximise the net benefit, and should aim to limit the inequity that may arise from a conflict of interest between individuals and society as a whole.

Some human activities increase the overall exposure to radiation and are termed "practices". Other human activities can decrease the overall exposure by influencing the existing causes of exposure and are termed "intervention". Exposures are categorized into three types: occupational exposure, which is the exposure incurred at work, and principally as a result of work; medical exposure, which is principally the exposure of persons as part of their diagnosis or treatment; and public exposure, which comprises all other exposures. In practices and in intervention, it will often be virtually certain that exposures will occur, and their magnitude will be predictable, albeit with some degree of error, but sometimes there will be a 'potential' for exposure, but no certainty that it will occur.

[7] Detriment represents the combination of the probability of occurrence of a harmful health effect (namely the inferred risk) and a judgement of the severity of that effect, adopting for this purpose a multi-dimensional concept. The principal components of the ICRP concept of detriment are the following stochastic quantities: the probability of attributable fatal cancer, the weighted probability of attributable non-fatal cancer, the weighted probability of severe hereditary effects and the length of life lost if the harm occurs.

Under this conceptual framework, it is recommended (and established by international standards), a system of radiation protection for practices and for interventions.

Practices

Practices are human endeavours that add radiation exposure to that which people normally incur due to background radiation, or that increase the likelihood of their incurring potential exposure. The system of radiological protection for proposed and continuing practices is based on the following general principles.

- *The justification of a practice*: No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.

- *The optimisation of protection*: 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 exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements.

- *The restrictions on individual dose and risk*. The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit.

These principles are applied prospectively at the planning stage of any practice, to the design, operation and decommissioning of the practice and its radiation sources. Before the introduction of a practice delivering exposure, an extant dose will exist. Following its operation and even after its decommissioning, there will be an *additional* dose attributable to the practice. The principles are applicable to the control of this attributable additional dose and not to the extant dose.

Under certain conditions, sources used in justified practices can be exempted from regulatory requirements if the individual additional doses attributable to the source are insignificant, e.g., below around 0.01 mSv/y or about 1/100th below the lower value of what is incurred annually from natural background radiation.

The justification of a practice delivering exposure requires that all relevant factors be considered prior to the adoption of the practice. Pertinent factors include those related to the radioactive substances that are expected to be discharged to the environment or to remain as radioactive residues in human habitats after the decommissioning of the practice.

The optimization of protection for practices requires the selection of the best radiological protection option for any source, under the prevailing social and economic circumstances. This optimum option will be expected to deliver doses that are considered as low as it be reasonably achievable doses, taking into account economic and social factors. For a justified practice delivering exposure, all pertinent factors should be taken into account in the optimization process, which may be carried out using optimization techniques recommended by the ICRP [e.g., ICRP, 1983].

The application of the justification and optimization principles to practices may introduce individual inequities. Inequities are caused by the possibly wide spatial distribution of exposures, which may involve people who are not direct beneficiaries of the practice. They can also be attributed to the potentially long-

term temporal distribution of exposure, which may affect future generations. In order to limit these inequities and to allow for exposures to multiple sources, the ICRP recommends applying stringent individual dose restrictions to the exposure expected to be delivered by individual sources and to the exposures predicted to be aggregated by all regulated practices. In a simplistic formulation, the exposure restrictions to regulated practices are termed *dose limits* and the exposure restrictions to sources are termed *dose constraints*.

Dose limits are established for workers and members of the public. These are values of effective dose or equivalent dose to individuals from practices that shall not be exceeded. The aim of the dose limits is to establish, for a defined set of practices, and for regular and continued exposure, a level of dose above which the consequences for the individual would be widely regarded as unacceptable.

The scope of dose limits for public exposure is confined to the doses incurred as the result of practices. Doses incurred in situations where the only available protective action takes the form of intervention are excluded from that scope. Separate attention is paid to potential exposures. The limit for public exposure is as an effective dose of 1 mSv in a year, namely a duplication of the lower value of natural background exposure. However, in special circumstances, a higher value of effective dose could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv per year. Limits are also needed for the lens of the eye and skin, since these tissues will not necessarily be protected against deterministic effects by the limit on effective dose, of 15 mSv for the lens in a year and 50 mSv in a year for the skin averaged over any 1 cm^2, regardless of the area exposed. All these are values that would be only just short of unacceptable for continued exposure as the result of deliberate practices the use of which is a matter of choice. This does not imply that higher doses from other sources, such as many natural sources, should be regarded as unacceptable. The existence of these sources may be undesirable but is not a matter of choice. The doses can be controlled only by intervention, which will also have undesirable features.

The ICRP also emphasizes that concerned national authorities and, as appropriate, relevant international organizations should consider situations where there could be a build-up of the prolonged components of the exposures attributable to all regulated practices as a result of the accumulation of radioactive residues from continuing practices. The aim should be to prevent that the aggregated individual additional doses attributable to all current practices and to predictable future practices exceed the dose limit of 1 mSv/y.

The dose constraints apply to doses expected to be delivered by a specific source within a practice. The ICRP recommends that the maximum value of the dose constraint to be used in the optimization of radiological protection for a single source should be less than l mSv/y, and that a value of no more than about 0.3 mSv/y would be appropriate. It also stresses that consideration should be given to exposure situations where combinations of transitory and prolonged exposures or a build-up over time of prolonged exposures from a source could occur. In these situations, ICRP recommends verifying that appropriate dose assessment methods are used for ensuring compliance with the established dose constraint. The assessment should take account of any reasonably conceivable combination and build-up of exposures. If, in a particular situation, such verification of compliance is not feasible, the ICRP considers it prudent to restrict the prolonged component of the individual dose from the source with a dose constraint of the order of 0.1 mSv in any given year during the operational lifetime of the source.

For occupational exposure the current limits on effective dose are 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. The 5-year period would have to be defined by the regulatory agency, e.g. as discrete 5-year calendar periods. The basis for the control of the occupational exposure of female workers who are not pregnant is the same as that for men. Once pregnancy has been declared, the conceptus should be protected by applying a supplementary equivalent dose limit to the surface of the woman's abdomen (lower trunk) of 2 mSv for the remainder of the pregnancy. These occupational dose limits apply to workers. A worker is any person who is employed, whether full time, part time or temporarily, by an employer, and who

has recognized rights and duties in relation to occupational radiological protection. Workers incur exposure voluntarily (namely, they know that they will be exposed as result of their occupation) and they are individually monitored (namely, the exposure they incur is well known). Occupational exposure is considered exposure of workers incurred in the course of their work, with the exception of excluded exposures and exposures from exempt activities involving radiation or exempt sources; any medical exposure; and the normal local natural background radiation. For occupational protection there is an obvious dose constrain of 20 mSv per year.

Interventions

Interventions are human activities that seek to reduce the extant radiation exposure, or the extant likelihood of incurring exposure which is not part of a controlled practice. The system of radiological protection for intervention is based on the following general principles:

- The proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention.

- The form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised.

An initial feature of the system is to demonstrate that the proposed intervention will be justified, i.e. do more good than harm, and afterward that the form, scale, and duration of the intervention have been chosen so as to optimise the protection. The processes of justification and optimisation both apply to the protective action, so it is necessary to consider them together when reaching a decision. Justification is the process of deciding that the disadvantages of each component of intervention, i.e. of each protective action, are more than offset by the reductions in the dose likely to be achieved. Optimisation is the process of deciding on the method, scale and duration of the action so as to obtain the maximum net benefit. In simple terms, the difference between the disadvantages and the benefits should be positive for each protective action adopted and should be maximised by settling the details of that action.

The justifiability of a particular intervention may be particularly tricky. Justification should be assessed by means of a decision- aiding process requiring a positive balance of all relevant long-term attributes related to radiological protection. In addition to the avertable doses, both individual and collective, other attributes include the following: the expected reduction in the anxiety caused by the situation, the reassurance to be provided by the intervention, and the social cost, harm and disruption that may be caused by the implementation of the protective actions. The results of such a decision-aiding process should be used as an input into a decision-making process which may encompass other considerations and may involve relevant stakeholders (*because, in paradigm choice there is no standard higher than the assent of the relevant community!, as stated in our initial motto!*).

The optimization of protective actions can be performed following the general approach to optimization of protection recommended by the ICRP in the context of practices. The optimum form, scale, and duration of the protective actions should be selected from the justified options of intervention.

In the particular case of accidents, the benefit of a particular protective action within a programme of intervention is to be judged on the basis of the reduction in dose achieved or expected by that specific protective action, i.e. the dose averted. Thus, each protective action has to be considered on its own merits. If the total dose in some individuals is so high as to be unacceptable even in an emergency, the feasibility of additional protective actions influencing the major contributions to the total dose should be urgently

reviewed. Doses causing serious deterministic effects, or a high probability of stochastic effects, would call for such a review.

National authorities (and, as appropriate, relevant international organizations) should predetermine specific reference levels (such as intervention levels, action levels, and intervention exemption levels) for particular exposure situations amenable to intervention. They can be conveniently expressed in terms of the avertable dose, or a related subsidiary quantity. The use of predetermined specific reference levels can facilitate timely decisions on interventions and the effective deployment of resources; however, an improper use may lead to inconsistencies with the principles of justification and optimization.

The ICRP also recommends the use of generic reference levels for intervention, particularly for the case of prolonged exposure situations [ICRP, 1999]. These levels can conveniently be expressed in terms of the extant dose. They are particularly useful when intervention is being considered in some prolonged exposure situations, such as exposures to high natural background radiation and to radioactive residues that are a legacy from the distant past. The ICRP, however, warns to use generic reference levels with extreme caution. If some controllable components of the extant dose are clearly dominant, the use of the generic reference levels should not prevent that protective actions are taken to reduce these dominant components. Either specific reference levels or case-by-case decisions can trigger these actions. Nor should the use of the generic reference levels encourage a “trade-off” of protective actions among the various components of the extant dose. A low level of extant dose does not necessarily imply that protective actions should not be applied to any of its components. Conversely, a high level of extant dose does not necessarily require intervention. With these provisos, the ICRP considers that an extant annual dose approaching about 10 mSv may be used as a generic reference level below which intervention is not likely to be justifiable for some exposure situations. Below this level, protective actions to reduce a dominant component of the extant dose are still optional and might be justifiable. In such cases, action levels specific to particular components can be established on the basis of appropriate fractions of the recommended generic reference level. Above the level below which intervention is not likely to be justifiable, intervention may possibly be necessary and should be justified on a case-by-case basis. Situations in which the annual (equivalent) dose thresholds for deterministic effects in relevant organs could be exceeded should require intervention. An extant annual dose approaching 100 mSv will almost always justify intervention and may be used as a generic reference level for establishing protective actions under nearly any conceivable circumstance.

Occupational exposures of emergency teams during emergency and remedial action can be limited by operational controls. Some relaxation of the controls for normal situations can be permitted in serious accidents without lowering the long-term level of protection. This relaxation should not permit the exposures in the control of the accident and in the immediate and urgent remedial work to give effective doses of more than about 0.5 Sv except for life-saving actions, which can rarely be limited by dosimetric assessments. The equivalent dose to skin should not be allowed to exceed about 5 Sv. Once the immediate emergency is under control, remedial work should be treated as part of the occupational exposure incurred in a practice.

CONTROVERSIES

There are controversies in radiation protection, many of them contesting the prevalent opinion on the dose-effect relation. Some controversies are presented hereinafter, under the quote “*when subject ceases to be a subject of controversy, it ceases to be a subject of interest*” [Hazlitt, ar.1800].

It is being argued that risk at low doses has been overestimated with extremes claiming that the risk at low doses would be non-existent or that the radiation effects could be even positive. The argumentation has evolved over the years including the following contentions: lack of experimental evidence, because no excess cancers have been detected at doses below approximately 100 mSv; DNA repair would efficiently

remove mutations, because an adaptive response process would create conditions of error-free repair; the dose-response relationship should be strongly curvilinear, with a de facto dose threshold, because the genetics of cancer development require several mutations for initiation, promotion and progression into malignancies (at least for some types of cancer); and radiation-induced apoptosis could be more efficient than radiation-induce carcinogenesis and would in fact create conditions for radiation hormesis that can even be enhanced by a potential stimulation of the immune response system.

Some of the controversies have been described elsewhere in the literature [see, *inter alia*, Beninson, 1996; Lindell, 1973; González, 2002, 2004]. A description of arguments and counterarguments in the controversies are presented hereinafter. It is hoped that these disagreements will be resolved in the years to come.

Contesting radiation-induced carcinogenesis

Mutations constantly occur in DNA and they are correctly repaired; for example, many arise simply from DNA miscopying during cell division. It is therefore argued that radiation-induced mutations must be reparable also. Repair should be absolute at low doses when the mutation frequency is so low, although miss-repairs may occur at higher doses when the mending mechanism becomes saturated. The counterargument, however, is that while it is true that simple DNA damage, as that from miscopying, is largely error-free repairable, radiation can cause destructive clastogenic damage. Interaction of radiation with DNA can produce double-strand lesions, particularly when DNA is condensed into chromosomes in a complex packed structure. Repair of double-strand breaks is difficult and inherently error-prone. Chromosomal deletions and translocations can be seen in microscopic analyses after radiation exposure and are used as an indicator of exposure.

Contesting the role of cell death

Cell death may occur because of: senescence, namely deterioration with age; necrosis, due to disease, injury, or failure of the blood supply; and, apoptosis, namely a DNA-programmed mutation-induced suicide caused inter alia by mutation. It has been argued that, if at low doses, the rate of mutation leading to apoptosis is higher than that leading to carcinogenesis, then low radiation dose exposure might have a hormetic effect cleaning the body of mutated cells and therefore reducing the risk of carcinogenesis. The counterargument however is that there is not any single evidence that the rate of mutation leading to carcinogenesis, which clearly prevail over the effects of apoptosis at high doses, becomes overcome at low doses by the rate of mutation leading to apoptosis

Contesting the process of carcinogenesis

It has been argued that for some cancers (e.g. colon cancer) From initiation to metastasis, several mutations are needed This would lead to a strongly curvilinear dose-response, which would present a de facto dose threshold. In fact, the argument is that, accepting that the probability of initiation is p = aD, if "n" mutations are required, the probability of cancer will be $p = aD^n$. E.g., for colon cancer, if n=7, such probability will be $p = aD^7$, which is an extremely curvilinear parabola with a *de facto* dose threshold. The counterargument is that this reasoning ignores that there is a 'natural' (no radiation-induced) mutation rate, S. Then, the probability of cancer being caused by these natural mutations would be $[1 - e^{-S}]^n$, and the cancer probability attributable only to radiation, Δp, is then given by the difference $\Delta p = [1 - e^{-(S+aD)}]^n - [1 - e^{-S}]^n$. But, because S >> aD, the difference Δp becomes approximately equal to aD. In sum, the probability appears to be approximately linear with dose for any n however large.

Contesting radio-epidemiology

Currently, radio-epidemiological data mainly arise from exposure at relatively high doses only, e.g., around ~1000 mSv. There are no epidemiological observations at very low doses. It is argued that the implication is

that no radiation risk can be inferred at low doses. The counterargument is that given the linear quadratic relationship, $p = (a D + b D^2) e^{-cD}$, the maximum level of detectability is given when the derivative $\delta p/\delta D = 0$. Differentiating $p= (a D + b D^2) e^{-cD}$ with respect to D, it is obtained $\delta p/\delta D = - cD + a + 2 b D$. Equalling $\delta p/\delta D$ to zero and operating algebraically it results, $cD_m = [(a/b) + 2D_m] / [(a/b) + D_m]$, where D_m is the dose that would maximize p, i.e. which would facilitate epidemiological observations. Operating with typical values from observations, it result that the doses that maximize epidemiological observations is $Dm \cong$ 1000 to 2000 mSv.

Contesting the dose-reduction factor

It is argued that the DDREF should be 1 rather than 2 and that therefore the risk factor is 0.01%/mSv rather than 0.005%/mSv. The calculation of DDREF result from relating the probabilities from the linear-quadratic dose relationship, $p = a D + b D^2$, and a linear relationsihip from the origin to the level of dose at which data exists $p = a D$. The probability per unit dose, or risk, would be $risk_{quadratic} = (a D + b D^2)/D = a+bD$, in the first case, and $risk_{linear} = a$ in the second case. Since DDREF = $risk_{quadratic}$/ $risk_{linear}$, it result that DDREF = $(a+bD)/a$ = = 1 + (b/a)D. Where the linear component is similar to the quadratic component, $(b/a) \cong 1/1000$ mSv. As epidemiological observations are maximized for $D \cong$ 1000 - 2000 mSv, under these conditions, the DDREF should be around 2 to 3, but it is noted that as time pass observations could be obtained at lower doses and the DDREF could be substantially lower.

Contesting the LNT paradigm

The model of proportionality between excess probability of harm and excess radiation dose above background levels is a cause of major confusion. It was termed according to the somewhat confusing LNT motto: “linear, non-threshold.” This terminology is unclear because and may be interpreted as expressing continuity in the absolute dose-response relationship, however small the dose might be. For purposes of radiation protection, however, the non- threshold concept at doses below background doses is not relevant. The higher background doses are those pertinent for purposes of public protection, and it is not feasible to shield people in high background areas against doses attributable to activities carried out in low-background areas. As few people doubt that doses approaching hundreds of mSv/y will increase the chance of deleterious effects, it would appear implausible that increments of dose above such values would change the slope of the dose-response and turn the correlation into one of positive health effects.

Contesting detectability limits

Because radiation is a weak carcinogenic, it is practically impossible to detect, and therefore attribute, effects at low doses due to statistical fluctuations. When an ‘exposed’ cohort or group of people, constituted by “N” people, who incurred “E” cancers, being subjected to a “n” probability of ‘natural’ (no-radiation induced) cancers, and a ‘p_D’ probability of ‘radiation’ induced cancers, is compared with a ‘control’ (no exposed) group of “N” people, who incurred “C” cancers and were subjected to the same “n” probability of ‘natural’ cancers, the difference E-C, i.e. the difference between $E = n N + p_d D N$, representing the number of cancers in the exposed group, and $C = n N$, representing the number of cancers in the control group, is very difficult to precise. The The standard deviation of such difference is $\sigma = \sqrt{(2 n N + p_d D N)}$. If the excess cancers are to be detected with a statistical confidence of 95%, $E – C > 2 \sigma$. Operating algebraically, and as $n >> p_d D$, the result is that $N >$ constant / D^2, where the constant = $8 n / p_d^2$, which is the equation giving the number of people, N, needed for detecting excess cancers at dose D. This fundamental equation for the epistemology of radiation effects can be represented in a log-log plane of coordinates N vs. D, as a straight line dividing the plane between a region (above the line) of epidemiological detectability, and therefore, provability, versus a region (below the line) of epidemiological undetectability, and therefore unprovability. In the region below the line radiation effects are not attributable to radiation exposure although radiation risk can still be inferred (see hereinafter).

Contesting the no-threshold model for risk inference

It is argued that the possibility of a risk threshold will influence radiation protection dramatically. The counterargument is that the certainty of a threshold may influence radiation protection, but its uncertain possibility should not challenge the current paradigm. Nominal statistical uncertainty distribution for excess lifetime risk of solid cancer mortality among atomic-bomb survivors has been investigated, in particular the uncertainty distribution for excess lifetime risk for low-LET radiation at low doses and dose rates for the general United States population [NCRP, 1997]. After taking account of various reduction factors (such as DDRF) the distribution is log-normal with on confidence limits of 1.2–8.8%/Sv On this basis, the uncertainty of a threshold has been modelled [Land, 2002]. Assuming a 20% probability of threshold, the cumulative probability still presents a 95% upper limit of just below 8.8%/Sv. Assuming a 50% probability of threshold, the 95% upper limit is around 7%/Sv. Assuming a 80% probability of threshold, namely a very high probability of threshold, given the current uncertainties the 95% upper limit is still as high as 5%/Sv, namely around the same value used in current radiation protection standards. In sum, given the epistemological limitations of knowledge of radiation effects at low doses, the possibility of a threshold, with the uncertainties surrounding such possibility, should not influence radiation protection.

Contesting the applicability of a non-linear (threshold) dose-response relationship

A relevant question is an eventual relationship would be applicable in radiation protection practice. Within the current paradigm at an increment of dose ΔD correspond a proportional increment in the inference of risk (or probability) Δp, regardless the value of D. If the paradigm moves to a non-linear dose response, any increment of dose ΔD would produce different increments in the probability Δp (with the extreme of $\Delta p=0$ at certain dose for a threshold relationship), depending of the level of dose, D. Therefore, for the same level of increment of dose $\Delta D_2 = \Delta D_1$, it would correspond to different levels of risk, e.g. $\Delta p_2 >> \Delta p_1$, and therefore different radiation protection demands. In addition, this would make the summation of doses unfeasible. Thus, if a non-linear dose-response relationship is adopted, radiation protection would become extremely cumbersome.

Contesting the current radiation protection system

The current radiation protection system is very sophisticated, which as being considered extremely complicated and difficult to communicate. A main misconception affecting the understandability of the systems is meaning of LNT. It has induced much confusion, mainly but not exclusively among the public and their political representatives, over the issue of regulating low doses. People become astonished when they discover that the regulated public dose limit is much lower than the doses caused by natural background. In fact, decision makers rarely understand that the international radiation system has a dual objective: on the one hand, it is conceived to control (through dose limits and constraints and optimization of protection) prospective additional doses to background doses, which may result from the introduction of human endeavours termed practices; and, on the other hand, it aims to reduce extant doses (including high background doses) through a process termed intervention. The confusion is severe between, on one hand, limiting additional doses through prospective *a priori* planning and design of practices and, on the other hand, reducing extant doses through intervention with protective actions. A typical example of such confusion was the contradictory advice that decision makers received in Europe at the time of the Chernobyl accident. They were advised to apply dose limits intended for additional doses from practices when the situation called for reducing doses through intervention. Misunderstandings about the basic radiation protection philosophy are a major cause of the debate on LNT.

Contesting the current foundation on dose rather than risk

The current dosimetric quantification is being disputed and there are proposals to move from quantifying and controlling dose to controlling risk directly. Using risk as the protection quantity is not as simple as could

be believed. The first problem lies with the traditional definition (or lack of definition) of risk. A number of questions arise: Is risk an expectation or a probability? If it is defined as a probability, what probability? It is a frequentistic probability, such as those that can be derived from epidemiological evidence at high doses? Or is it a Bayesian, subjective, probability such as that inferred as a 'degree of believe' for low doses? Is it a probability proper, which cannot exceed a value of one (or 100%)? (E.g., p, in a year, lower than one)? Or is it the probability per year, or rate, dp/du, with age, u, which will exceed the value of one at a high age? If the probability rate is used, a "reference rate" can be obtained from the Gompertz-Makeham relationship as the lowest age-specific mortality rate currently found in any country for the various ages. Currently, in developed societies, such a lowest value is around 2 10^{-4} at age of around 10 years. The current occupational standards have taking account of the change in the Gompertz-Makeham relationship, namely the change in the total death probability rate versus age, following an exposure at the current limits of 50 mSv/year from age 18 to 65 years, for both males and females showing that the change is minimal. They also have assessed the death probability rate, namely the normalized probability density of the age of death from radiation-induced cancer, versus age, following exposure at 50 mSv/year (from age 18 to 65 years) and found a maximum pick at age around 70-80 years, which following the additive model is around 10^{-2} per year and following the multiplicative model is around 3 times higher. The integral of this relationship $\int_0^\infty$ provides the lifetime probability of dying from cancer caused by the irradiation.

Contesting the characterization of individual members of the public

The currently used critical group concept is being questioned. The critical group has been understood as a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and is typical of individuals receiving the highest dose from the given source The Chernobyl experience shows that in population groups that generally comply with the critical dose concept, doses to individuals varied by more than one order of magnitude [IAEA, 1991, 1996a, 2001b]. The concept of 'average member of the critical group' described in current standards is being replaced by the concept of 'representative person' who would be an individual receiving a dose that is representative of the more highly exposed individuals in the population.

Contesting the collective dose concept

The collective dose due to individual dose values between D_1 and D_2 from a specified source within a specified time period ΔT is defined as the integral, S, of D $(\delta N/\delta D)_{\Delta T}\ \delta D$ between D1 and D2, $S=\int_{D1}^{D2} D\ (\delta N/\delta D)_{\Delta T}\ \delta D$, and it is simplified as $S = \Sigma_i D_i N_i$. There is a mayor confusion on the concept of collective dose vis-à-vis the concept of dose. Dose is an intensive quantity while collective dose is an extensive quantity. As other extensive quantities, collective dose in isolation is meaningless; it has to be used per unit of some other quantity, such as a quantity representing the unit practice, e.g., energy produced, in the case of the practice of nuclear energy generation. Moreover, collective doses are not intended to be use in absolute terms but as difference between two collective dose options, such as those arising from different protection options, for deciding the optimized option. For instance, if it is necessary to decide between a protection option 1, delivering a collective dose S_1, and a protection option 2, delivering a collective dose S_2, if $S_1 > S_2$, other conditions being the same, option 2 would be preferable, even if the higher individual doses are the same. One complication may occur when collective doses are integrated over time. If the time period is large and even infinite (such as in radioactive waste disposal options) the relevance of the results can be distorted. It should be recalled however that a difference between two time infinite integrals, e.g. $\int_{\tau 1}^{\infty} - \int_{\tau 2}^{\infty}$ is equal to a finite integral between the starting times, $\int_{\tau 1}^{\tau 2}$.

Moreover, an important reason for using collective dose is the Bo Lindell's theorem [Lindell, 1973], which shows that following a continuous practice the individual dose in the long time is equal to the individual dose committed at the first year. As a result, in order to limit future doses from today's continuing practices, it

would be necessary to restrict all doses committed over time by a given unit practice, i.e. to limit the collective dose commitment per unit practice.

CHALLENGES

A number of challenges are confronted by the sciences of radiation effects and radiation protection. They are presented hereinafter recalling the dictum "*The present invents itself…in the act of challenging the future throwing away previous accomplishments*" [de Certeau, 1974]. Many of these challenges are being addressed at the moment by UNSCEAR. But their resolution continues to be a challenge. I would encourage young scientists to engage themselves in researching all the challenging phenomena described below. The outcome may influence our current understanding and practice of radiation protection.

Are the estimates of radiation health effects a closed book?

The time scale of the phenomena of radiation health effects limits knowledge. Physical and chemical phenomena occur in a diminutive time scale, above around 10^{-15}seconds**.** The initial biological phenomena occur in a time scale from 1 millisecond up to days. The epidemiological manifestation of effects may, in the case of stochastic effects, take place tens of years ahead. In the middle there is the physiological progress, including the potential effects on the immune system, of which we know very little. The estimates of radiation health effects comprise a book that is far to be closed.

What are the thresholds for deterministic effects when exposures are protracted?

The various dose thresholds for deterministic effects following acute exposure are relatively well known from experience in radiotherapy and in few accidents. However, the data for protracted exposure is scarce. Might there be deterministic effects for which the logistic function of probability versus dose is as elongated as appearing to be a linear function of dose?

Are there other targeted stochastic effects?

Chernobyl workers, atomic bomb survivors, and radiotherapy patients seem to suffer a higher risk of cardiovascular diseases. There is evidence of a high incidence of opacities of the crystalline in people exposed (e.g. in Chernobyl workers). Are these other targeted effects, deterministic effects where the logistic function is elongated over time?

What is the relevance of the 'non-targeted' effects?

A number of non-targeted effects have been reported. *Adaptive response*, or the induction of responses in cells by very low doses of radiation resulting in an enhanced resistance to much larger exposures, appears to occur in experiments but has not been definitively proved in humans. *Genomic instability*, or an increased rate of acquisition of alterations in the genome following irradiation, has been widely reported. *Bystander effects*, or the ability of cells affected by radiation to convey manifestations of damage to other cells not directly targeted by radiation, have challenged the paralogism of effects occurring, namely the specious logic of a casual relation between interaction and mutation, a fallacious reasoning superficially appearing logical (bystander effects show that if radiation mutates a gene in a cell nucleus, no affected genes in other cells can mutate!). *Abscopal effects*, or significant tissue response to irradiation in tissues definitively separated from the radiation exposed area seems to be frequent in radiotherapy procedures [H&ET, 2004]. *Clastogenic plasma factors* seem to be responsible of the fact that irradiated plasma can induce detrimental effects in unexposed cells. Do these 'non-targeted' effects affect our current understanding on radiation effects or should we assume that epidemiological estimates encompass all effects, targeted and non-targeted?

What about the immune system?

UNSCEAR has studied the potential response of the immune system to radiation exposure. But the results of the evaluation seem to be ambiguous. Does radiation exposure inhibit the system or enhance its response, or is exposure irrelevant?

Is the value of the second derivative of dose (namely, changes in the dose rate) influence radiation risk?

If adaptive response exists and its dynamics vary with dose rate, should changes in dose rate, $\delta D^2/\delta t^2$, influence the risk, $\Delta p/\Delta D$?. $\Delta p/\Delta D$ is estimated to be approximately equal to 0.005 %/mSv, but in epidemiological studies where the cohort have been subjected to $\delta D^2/\delta t^2 >> 0$ (e.g. the LSS). Should this be different for radiation exposure situations presenting a low $\delta D^2/\delta t^2$? In most exposure situations the value of $\delta D^2/\delta t^2$ is negligible. One of the few radiation exposure situations where $\delta D^2/\delta t^2$ is relatively high are those exposure to cosmic rays incurred by aircraft crew and passengers in the ascendance of aircrafts. Could be the case that radiation exposure situations with low $\delta D^2/\delta t^2$ present a risk per unit dose, $\Delta p/\Delta D$, which is different than their risk extrapolated from LSS estimates?

What are the effects of radiation in the various cell organelles?

Radiation does not interact only with the nuclear DNA. It also affects all the cell, including its many organelles. The smooth endoplasmic reticulum synthesizes lipids, phospholipids, and steroids. The rough endoplasmic reticulum covered with ribosomes translates the RNA of a protein destined for the secretory pathway. The lysosymes damage bacterial cell walls. The Golgi apparatus packages proteins into membrane-bound vesicles inside the cell before the vesicles are sent to their destination. The mitochondria supply cellular energy and are involved in tasks such as signalling, cellular differentiation, and cell death, as well as maintaining control of the cell cycle and cell growth. The cytoskeleton, a network of interconnected microfilaments and microtubules, gives the cell shape and mechanical resistance to deformation, allows cells to migrate, is involved in many cell signalling pathways and in the uptake of extracellular material, segregates chromosomes during cellular division, is involved in cytokinesis, provides a scaffold to organize the contents of the cell in space and for intracellular transport (for example, the movement of vesicles and organelles within the cell), and can be a template for the construction of a cell wall.

The effects of radiation in the cell organelles have been only partially studies for the mitochondria. There are experimental difficulties for these studies, but they might be essential to understand better the radiation effects at cellular level. For instance, it has been argued that quantum phenomena might be feasible at the cytoskeleton [Penrose, 1994]. Are quantum mechanisms involved in the genesis and propagation of radiation-induced mutations?

NAVIGATION

A navigation proposal is presented hereinafter after recalling Seneca's dictum "*errant consilia nostra, quia non habent quo derigantur; ignoranti quem portum petat nullus suus ventus est*" (*If one does not know to which port one is sailing, no wind is favourable*)[8]. The basic question currently confronted by the radiation protection community is: Towards which port should radiation protection be sailing?

My proposal is that radiation protection should navigate towards a harmonized and sustainable worldwide regime. And with that purpose, I would suggest the following initiatives:

[8] Seneca –Epistulæ Morales ad Lucilium (Moral Letters to Lucilius)

- **Let's build a comprehensive set of mandatory international standards using the international basic safety standards for radiation protection as a basis.**

Since among the international intergovernmental organizations involved in radiation safety, the IAEA is the only one specifically authorized under the terms of its Statute to establish radiation safety standards[9], not surprisingly the first endeavour to establish international radiation protection requirements was made at the IAEA. The IAEA's Board of Governors first approved radiation protection and safety "measures" in March 1960 [IAEA 1960, 1976], when it was stated that "the IAEA's basic safety standards…will be based, to the extent possible, on the recommendations of the ICRP. The IAEA's Board of Governors first approved basic safety standards in June 1962, and these were published as Safety Series No. 9 [IAEA 1962], a revised version was published in 1967 (IAEA 1967). At the beginning of the 1980's a further— comprehensive—revision was carried out. This was jointly sponsored by the IAEA and two other organizations of the UN family, ILO and WHO, and also by the OECD/NEA. The resulting text was published by the IAEA as the 1982 Edition of Safety Series No. 9 [IAEA 1982]. At the end of the 1980's, ICRP revised its standing advice and issued its 1990 recommendations [ICRP 1991] in the light of which relevant organizations of the UN family and other multinational agencies promptly started to review their own radiation safety standards. Thus, taking account of the new developments and within the frame- work of Inter-Agency Committee on Radiation Safety, the IAEA, FAO, ILO, OECD/NEA, PAHO, and WHO established a Joint Secretariat— coordinated by the IAEA—for the preparation of new International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, which came to be commonly referred to as the Basic Safety Standards (or BSS) [IAEA 1996]. The BSS provide the basis for consolidating an international system of radiation protection standards.

- **Let's formalize an international system for appraising compliance with standards.**

In order to meet its second statutory responsibility—to provide for the application of its standards—the IAEA carries out a number of safety related activities. These include fostering information exchange, encouraging research and development, providing technical assistance to developing Member States, promoting education and training and, notably, rendering appraisal services, such as radiological assessments of contaminated environments, the evaluation of accidents, carried out by international peers. Any Member State may request the IAEA to provide for the application of the international standards through appraisals

[9] Since its creation in 1957, the IAEA has performed two main safety related functions that are precisely described in its Statute as to establish standards of safety for protection of health and to provide for the application of these standards at the request of a State, which are unique among the functions of international organizations. Thus, namely: establishing standards of safety for the protection of health against the detrimental effects attributable to radiation exposure; and providing for the application of those standards at the request of any State. Thus, the IAEA has established a body of standards in the fields of radiation safety, radioactive materials transport safety, radioactive waste safety, and nuclear safety. The standards in each area have tended to follow a common general pattern—a set of fundamental principles, a set of mandatory requirements, and a large number of documents containing more detailed guides. Over the years, the IAEA safety standards have been published in the IAEA Safety Series, one of the publications series of the IAEA. Originally, there was no distinction in status between the various safety related documents published in the Safety Series. In 1989, however, following a major expansion of the IAEA's safety related activities, the IAEA introduced a hierarchical structure for its Safety Series publications, which was further adjusted when the series became known as the Safety Standards Series of the IAEA. Such hierarchical structure is as follows: Safety Fundamentals, stating basic objectives, concepts and principles; Safety Requirements, stating basic requirements, which must be fulfilled in the case of particular activities or applications; and Safety Guides, containing recommendations related to the fulfilment of the basic requirements stated in the Standards. The Safety Requirements encompass the basic requirements that must be satisfied to ensure safety for particular activities or application areas. These requirements are governed by the basic objectives, concepts, and principles presented in Safety Fundamentals. The publications in this category do not present recommendations on, or explanations of, how to meet the requirements. The written style used in Safety Requirements accords with that of regulatory documents since the requirements established may be adopted by Member States, at their own discretion, for use in national regulations. Regulatory requirements are expressed as "shall" statements. Safety Requirements are self-standing and do not cite standards of other organizations over which the IAEA has no control. They also are published in all official languages of the IAEA.

by international peer reviewing. Just as an example, recently, the IAEA performed an international peer review of the biosphere modelling programme of the US Department of Energy's Yucca Mountain Site Characterization Project [IAEA, 2001d], and a comprehensive appraisal of transport radiation safety took place in the United Kingdom [IAEA 2002]. The time seems to be ripe for the formalization and generalization of these appraisal services.

- **Let's unravel the cold-war and other past practices radiological legacy.**

The IAEA has initiated an unprecedented effort to unravel the radiological legacy of the cold war. International assessments has been performed on the radiological conditions at Bikini Atoll, including prospects for resettlement [IAEA, 1998b]*;* the radiological situation at the Atolls of Mururoa and Fangataufa [IAEA, 1998c]; the radiological conditions at the Semipalatinsk Test Site, in Kazakhstan, a preliminary assessment with recommendations for further studies [IAEA, 1999d], and, the radiological conditions of the Western Kara Sea, which include an assessment of the radiological impact of the dumping of radioactive waste in the Arctic Seas [IAEA, 1999f]. But all these studies, however important they are, just represent one drop of water in an immense ocean. Much more is needed to unravel the radiological legacy of the cold war and other *non-sancta* practices.

- **Let's consolidate the international system for reviewing radiological accidents.**

After reviewing the Goiâna accident [IAEA, 1986], the IAEA launched and unprecedented effort for reviewing radiological accidents in order that everybody could profit from the lesson learned. The system has its apex with the evaluation of the Chernobyl accident [IAEA, 1991]. The system has been very successful and should be consolidated.
The related issue of enhancing international emergency response is also high on the international agenda, particularly after the 11 September events. Since the occurrence of the Chernobyl accident, the Notification Convention and the Assistance Convention have governed the international system of emergency preparedness and response. The IAEA obligations under the conventions are to notify Member States, provide authoritative information, and to assist in the emergency response. It is also essential to consolidate this system.

- **Let's foster an international understanding for limiting discharges to the environment**, I order to ensure the protection of humans and their habitat, as discussed in the recent Conference on *Protection of the environment from the effects of ionizing radiation* [IAEA, 2004b].

The control of discharges of radioactive materials into the environment is the area where international consensus has been achieved at an early stage. Recently, such a consensus has been consolidated into new regulations [IAEA 2000c]. However, a new issue is arising internationally for radiation protection of the environment as a whole rather than of human beings in isolation. The question is: if each individual human being is protected against radiation exposure, now and in the future, is the "environment" protected as well? [Holm 2004]. On this topic all roads led to Stockholm, where the international conference addressed the remaining open issues [IAEA, 2004b]. An international understanding seems to be promptly required for limiting discharges to the environment.

- **Let's ensure proper protection conditions for workers**, as discussed in the recent Conference on *Occupational radiation protection: protecting workers against exposure to ionizing radiation* [IAEA, 2003c].

One of the most successful areas in the internationalization of radiation protection has been that of the protection of workers. A recent International Conference on Occupational Radiation Protection, organized

by the IAEA and ILO and hosted by the Government of Switzerland, revisited the international achievements in this field (IAEA 2003a). The Conference identified a number of unresolved issues, including: the applicability of the international standards to natural exposures (there is no international agreement on what "natural" occupational exposure to exclude), the attributability and imputability of occupational harm (with the radiation workforce aging, around a quarter will develop cancers that will probably be attributed to their work-life exposure, however low such exposure may be), and the protection of the female worker and of the unborn. The Conference findings are being converted into an International Action Plan on Occupational Radiation Protection.

- **Let's provide for the protection of patients undergoing radio-diagnosis or therapy**, as discussed in the recent Conference on *Radiological protection of patients in diagnostic and interventional radiology, nuclear medicine and radiotherapy* [IAEA, 2001c].

Another issue that is high on the international agenda is that of the radiological protection of patients undergoing radiodiagnostic or radiotherapeutic procedures. Following a successful international conference in Málaga, Spain [IAEA 2001d], an international action plan has been approved by the IAEA and is being promptly implemented [Mettler, 2004]. Patients have been basically ignored in radiation protection standards. Following the Malaga conference, the time is ripe for change.

- **Let´s manage all radioactive waste safely**, as discussed in the Conferences on the *safety of radioactive waste management* [IAEA, 2000b] and on *Issues and trends in radioactive waste management* [IAEA, 2003f].

In March 2000, mindful of the impending entry into force of the Joint Convention on the safety of spent fuel and radioactive waste management, the IAEA organized the Córdoba Conference on the safety of radioactive waste management [IAEA, 2000b], a major international meeting with the objective to identify issues needing to be resolved at the international level in order to assist Member States to address their obligations under the Convention. The Córdoba Conference was a landmark event in radioactive waste safety, co-sponsored by the NEA and the EU and hosted by the Spanish government. It was attended by senior regulators and operators from all countries with large nuclear programs and by many interested parties from countries faced with the problems of safety and cost effectively managing the wide and diverse range of radioactive wastes that arise both from the nuclear fuel cycle and from the extensive uses of radioactive materials in industry, medicine and other areas. It also considered the large amounts of radioactive wastes generated in an equally diverse range of human activities that contain elevated levels of naturally occur- ring radioactivity. The conference was attended not only by technical specialists but in addition by a number of broader stakeholder parties with an interest in the safety of radioactive waste management.[10] The Córdoba Conference's conclusions have focused much of the IAEA's work in the area of radioactive waste safety, forming the basis for the International Waste Safety Action Plan approved by the

[10] The Córdoba conference reached a number of important conclusions, identifying in particular a number of needs, namely: 1) to establish a common and coherent framework within which to manage all radioactive waste types in a safe and cost effective way; 2) to clearly identify the safety implications of storing radioactive waste for extended periods of time and the sustainability of such practice; 3) to move forward with developing international consensus on safety standards for geological disposal of high level waste, including spent fuel considered as waste; 4) to develop a coherent and consistent approach to the removal of materials from regulatory control; 5) to ensure that safety standards for radioactive waste safety and the technology needed to achieve compliance with these standards are available and applied consistently through- out the world, and that information important to the longer term safety of waste management (and particularly waste disposal facilities) is preserved and passed on to succeeding generations in a manner that will provide such generations with an assurance of the safety of such facilities; and, 6) finally, to address the effective inclusion of all stakeholder parties interested and affected by waste management facilities and decisions regarding their safe development.

Board of Governors and endorsed by the IAEA General Conference in September 2001. Events since Córdoba have also influenced the work of the IAEA, and not least the welcome progress made in the development of geological disposal facilities, particularly in the United States, Finland, and Sweden. But also on a much darker side, the events of 11 September have focused attention sharply on the potential threat that could be created by malevolent acts involving radioactive materials, including radioactive waste. The latter has given rise to much introspection on the safe and secure handling, treatment, storage and disposal of radioactive waste.
All these issues were reconsidered at a Conference in Vienna on Issues and trends in radioactive waste management [IAEA, 2003f], the main conclusion of which can be summarized as follows: work towards the consolidation of an international regime for the safety of radioactive waste management. The findings of the Vienna Conference will result in an enhanced International Action Plan.

- **Let's verify that radioactive material is transported safely**, as discussed in the recent Conference on *safety of transport of radioactive material* [IAEA, 2003d].

Another topic that is causing much concern among politicians is the radiation protection aspects of the transport of radioactive materials. The IAEA has, since 1961, issued international regulations for the safe trans- port of radioactive materials, which are incorporated in the UN recommendations for the transport of dangerous goods and then into the safety code of the transport "modal" regulations. An important issue is that, for the first time, countries are agreeing to be internationally appraised for verifying that they apply the transport regulations. However, as the global concern about transport safety continues, the IAEA held the recent international conference to discuss and attempt to resolve all remaining issues [IAEA, 2003d].

- **Let's arrange for the safe decommissioning of installations**, as discussed in the recent Conference on *Safe Decommissioning for Nuclear Activities* [IAEA, 2003b].

Radiation protection in decommissioning is a growing issue related to the safety of radioactive residues. A large number of NNPs and other installations where radioactive substances are being used will have to be decommissioned in the near future. The problem being faced by the radiation protection community is that there are no internationally recognized criteria for defining when the remaining radioactivity after de-commissioning can be considered safe. These issues were discussed recently at the international conference [IAEA, 2003b], and its findings are expected to feed an international action plan on this critical issue.

- **Let's get a consensus on remediation of environments containing radioactive residues**, as discussed at the 1999 *International Symposium on Restoration of Environments with Radioactive Residues* [IAEA, 2000a].

The presence of radioactive residues in human habitats is difficult to handle. These residues may result from the discontinuation and decommissioning of a regulated practice or from other past human activities and events, including accidents. For regulated practices, the recommended dose constraints and dose limits should be applied prospectively to the exposure expected to remain after the discontinuation of the practice—for instance, at the site of a decommissioned installation. In principle, the applicable dose constraint may be expected to be no higher than the dose constraint used during the operational phase of the practice. How- ever, there is not necessarily a commonality on the basis of which to presume equality between the dose constraint applied before the discontinuation of a practice and that applied afterwards. If the operational dose constraint was very low, maintaining it in the post-decommissioning phase could introduce an unreasonable restriction. For radioactive residues from other past human activities and events that were not regulated as practices, the need, form, scale and duration of protective actions should be determined on a case-by-case basis. This should be done following the recommended principles of justification of intervention and optimization of the protective actions, rather than through pre-selected

individual dose restrictions. If necessary, the recommended generic reference levels of existing dose may be used as guidance. How- ever, in cases where the origins of the situation are traceable and where those who produced the residues can still be made retrospectively liable for the protective actions, national authorities may consider applying a specific restriction to the individual doses attributable to the residues constraining the resulting doses to levels below those resulting from the optimization process. For this purpose, additional protective actions may be required from those who created the situation. Such specific dose restriction, however, may be higher than the dose constraints and dose limits applied to practices[11]; this is a relevant topic for the future and it need of international consensus.

- **Let's deal with the new threat of radiological terrorism and ensure continuing strengthening of control over radioactive sources, control from 'cradle to grave'**, as discussed in the recent conferences on. *Safety of radiation sources and security of radioactive materials* [IAEA, 1998], *National regulatory authorities with competence in the safety of radiation sources and the security of radioactive materials* [IAEA 2001a] and, *Security of radioactive sources* [IAEA, 2003a].

After the terrorist attacks of 11 September, increasing public apprehension about the security of radioactive sources has evolved worldwide. Could a radioactive source combined with a conventional explosive be turned into a devastating tool for terrorists?[12] The U.S. media promptly dubbed the new menace a "dirty bomb"—a nickname that does not alleviate public uneasiness. The possibility of this *mélange* being used with malevolent purposes certainly exists; however, the real issue is whether radioactive sources should be the focus of our interest when hundreds of dangerous chemicals and biological agents are readily available for harmful terror- ist acts. If detonated in a city, a dirty bomb will certainly disseminate radioactive particles scattering some radio- active contamination. However, the effects of such a device cannot be compared to the catastrophic effects of a nuclear, chemical, or biological weapon, but the public will not necessarily

[11] Disruptive protective actions, such as evacuation or other restrictions in the "normal" living conditions of people, may be required after accidents that have released radioactive substances into the environment. Eventually, in order to return to "normality," such actions may need to be discontinued at some stage in spite of the continuous presence of a residual exposure. The simplest basis for justifying the discontinuation of intervention after an accident is to confirm that the exposures have decreased to the action levels that would have prompted the intervention. If such a reduction in exposure is not feasible, the generic reference level of existing dose below which intervention is not likely to be justifiable could provide a basis for discontinuing intervention. However, it may be difficult to discontinue protective actions that have been in force for many years. The decision may not be acceptable to the exposed population and the social pressures may override the benefit of discontinuing the intervention. In these cases, the participation of the stakeholders in the decision-making process becomes essential. After intervention has been discontinued, the remaining existing dose should not influence the normal living conditions in the affected area (including decisions about the introduction of new practices), even if such a dose is higher than that prevailing in the area before the accident.

[12] The 11 September attacks demonstrated a new kind of malevolence, characterized by the perpetrators' intent to induce widespread panic and harm among the civilian population, the ability to work with modern technologies, and a suicidal approach. These characteristics open up new dimensions to the problem of securing potentially harmful substances in general, including radioactive sources. No tight security measures are usually applied to chemical or biological products in general and radioactive sources are not an exception. The security aim has traditionally been confined to preventing accidental ac- cess to the sources or petty theft (such as stealing shielding materials). Certainly, no sophisticated anti- terrorist security measures are commonly in place and even well regulated radioactive sources could be stolen and diverted with relative ease, as is the case for most chemical or biological substances. While the vast majority of radioactive sources are under the control of competent governmental regulatory authorities, the world is abundant in "orphan sources," or sources that have never been subject to regulatory control, or were initially regulated but eventually abandoned, lost, misplaced, stolen, or removed without authorization. Many industrial and medical radioactive sources are believed to be in this state, and serious incidents involving orphan sources have occurred in the newly formed States of the former USSR. Obviously, orphan sources are easier to divert than regulated sources and are prone to fall into malevolent hands. An embezzled source can be converted without major difficulty into a dirty bomb, particularly if the perpetrator is willing to disregard his or her personal safety.

perceive the difference. Thus, while a dirty bomb will not produce a large number of casualties, terror and psychological trauma will certainly follow its use. Following the trauma caused by the New York and Washington attacks, irresponsible statements by self-declared experts and media sensationalists have increased public fears and anxieties about the potential terrorist use of a dirty bomb. While the apprehension of the public is comprehensible, professionally the issue is not new, and therefore the perspective is more balanced. Long before 11 September, the need for securing radio- active sources was high on the agenda of the international health physics community and was an integral part of the radiation safety program of the IAEA. Security, or the prevention of unauthorized possession of radioactive sources, has always been an essential element of the IAEA's radiation safety activities. The BSS established international requirements for the security of radioactive sources, which demand inter alia that radioactive sources "be kept secure so as to prevent theft or damage. . . by ensuring that. . . control of a source not be relinquished. . . ."

Governments gradually became aware of the international dimensions of the security threat associated with radioactive sources. By 1998, hundreds of specialists and governmental representatives met at the first international conference on the issue, which was organized by the IAEA jointly with Interpol, the World Custom Organization, and the European Commission in Dijon, France [IAEA, 1998]. The Dijon Conference produced recommendations that the IAEA General Conference made into an international Action Plan to strengthen the global safety and security of radioactive sources. In December 2000, national regulators of radioactive sources met at an international conference convened by the IAEA in Buenos Aires, Argentina [IAEA 2001a]. The Buenos Aires Conference recommended reinforcing the Plan, which was subsequently revised and strengthened by the IAEA Board of Governors and General Conference in September 2001.

In face of the new reality the overall international strategy in the security of radioactive sources is being reviewed. The basic IAEA objectives remain: assisting Member States to create and strengthen national regulatory infrastructures to ensure that radioactive sources are localized, registered, secured and controlled from "cradle to grave." While this strategy is immutable, its application has to be adapted to the new security dimension. Before 11 September, it was targeted to breaches in security caused by innocent mistakes or petty theft. Today, the scope is being widened to include malevolence and terrorism. A number of new initiatives are being considered, including a precise fact-finding assessment of the global situation. A recent international conference in Vienna [IAEA 2003a] has addressed relevant issues; its findings have been converted into an international action plan.

- **Let's achieve legally binding instruments for proper control**, such as the recent *Code of conduct on the safety and security of radioactive sources* [IAEA, 2004a]

An important outcome of the international Action Plan to strengthen the global safety and security of radioactive sources, has been the establishment of a the (unfortunately) non-binding "Code of Conduct", a necessary but not sufficient condition for ensuring the security of radioactive sources. The Code of Conduct should be converted into a legally binding undertaking. International assistance to developing countries should be augmented (an unsecured source can be used malevolently anywhere) and IAEA non-member States should be involved. A system for appraising national compliance with international security criteria should be established. Significant radioactive sources should be easily identifiable and tracked and their physical characteristics should be more secure. Countries should be encouraged and helped to monitor border crossings for detecting illegal movement of sources and to locate orphan sources. Strengthening security during the transport of radioactive materials should be top priority on future agendas. Furthermore, the international emergency response capabilities called for by the Notification and Assistance Conventions must be enhanced. Education and training, particularly through the train-the-trainers approach, would be an essential element of any new initiative.

- **Let's help the developing world to achieve effective sustainable radiation protection infrastructures**, as discussed in the recent Conference on National infrastructures for radiation safety: towards effective and sustainable systems [IAEA, 2004c]

Regulatory infrastructures for radiation protection are weak in many countries. The IAEA had to launch a "Model (technical cooperation) Project" aimed at enhancing (and sometimes creating) a reasonable infrastructure in 52 of its Member States. The project has been expanded to cover 87 Member States. However, within the UN, there are about 50 countries that are not even Member States of the IAEA and where radiation protection infrastructures are probably non-existent.

- **Let's not forget that the world has 192 States all with radiation protection problems**.

It is an imperative of the radiation protection community to help those in biggest need and persuade them to be committed to helping each other. In this regard, let's benefit from good examples such as the Ibero-American Forum of Regulators and its Ibero-American Radiation Protection Network.

…and least but not last…,

- **Let's spread our achievements around the world**.

The time seems to be ripe for binding commitments for a harmonized, efficient and sustainable global radiation protection regime.

EPILOGUE

Over the last years, the advances of radiation protection have been extraordinary. They are perhaps unparalleled by any other discipline guarding human health against detrimental phenomena. However, a monumental radiation protection agenda lies ahead for national governments and the health physics community. The challenge will be to address controversies and challenges, effectively weighing their relative importance in comparison to other health, safety, and security problems that the world is facing today. This will require a global common understanding and a formal international consensus.

I would like to conclude the 2004 Sievert Lecture with a relevant suggestion:

- **Let's convince our political masters to work towards an International Convention on Radiation Protection**.

Because, there will be no protection for any of us unless there is protection for all!

Thank you for your attention…and patience.

REFERENCES

Beninson, 1996. Dan Beninson. *Risk of Radiation at Low Doses*. The Sievert Lecture at IRPA 9, Vienna, April 1996.

Clarke, 2004. Roger H Clarke. *Draft recommendations from ICRP at the start of the 21st century*. Health Phys 87:306 –311; 2004.

de Certeau, 1974. Michel de Certeau. *The Practice of Everyday Life*, ch. 7 (1974)

Feyerabend, 1975. Paul Feyerabend. *Against Method*, p. 21 (1975).

Gonzalez, 2002. Abel J. González. *The debate on the health effects attributable to low radiation exposure*. Pierce Law Rev 1(1/2) Fall; 2002.

González, 2004. Abel J. González. *Radiation Safety Standards And Their Application: International Policies And Current Issues*. Health Physics, Volume 87, Number 3, pp. 258-272 (del. April 2004)

Hazlitt, ar.1800. William Hazlitt, in Complete Works, vol. 20, (1932).

Holm, 2004. Lars E. Holm. *Current activities of the International Commission on Radiological Protection*. Health Phys 87:300 –305; 2004.

H&ET, 2004. Human & Experimental Toxicology, Volume 23, Issue 2, 1 February 2004, Arnold

IAEA, 1991. International Atomic Energy Agency. *The International Chernobyl Project: Assessment of Radiological Consequences and Evaluation of Protective Measures*. Vienna: IAEA, 1991.

IAEA, 1960. International Atomic Energy Agency. *The IAEA's health and safety measures*. Vienna: IAEA; INFCIRC/18; 1960.

IAEA, 1962. International Atomic Energy Agency. *Basic safety standards for radiation protection*. Vienna: IAEA; Safety Series No. 9; 1962.

IAEA, 1967. International Atomic Energy Agency. *Basic safety standards for radiation protection* (1967 edition). Vienna: IAEA; Safety Series No. 9; 1967.

IAEA, 1976. International Atomic Energy Agency. *The IAEA's health and safety measures*. Vienna: IAEA; INFCIRC/18/Rev. 1; 1976.

IAEA, 1982. International Atomic Energy Agency. *Basic safety standards for radiation protection* (1982 edition). Vienna: IAEA; Safety Series No. 9; 1982.

IAEA, 1988. International Atomic Energy Agency. The Radiological Accident in Goiânia. IAEA, VIENNA, 1988. STI/PUB/815. ISBN 92-0-129088-8.

IAEA, 1991. International Atomic Energy Agency. *The International Chernobyl Project: Assessment of Radiological Consequences and Evaluation of Protective Measures*. Vienna, 1991.

IAEA, 1996a. International Atomic Energy Agency. *Proc. Int. Conference: One Decade after Chernobyl, Summing up the Consequences of the Accident.* Vienna: IAEA, 1996.

IAEA, 1996b. Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organisation, OECD Nuclear Energy Agency, Pan American Health Organization, World

Health Organization. *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources.* IAEA Safety Series No. 115. Vienna: IAEA, 1996.

IAEA, 1998a. International Atomic Energy Agency. *Safety of radiation sources and security of radioactive materials*. Proceedings of an International Conference on the Safety of Radiation Sources and the Security of Radioactive Materials /jointly organized by the European Commission ... [et al.] and held in Dijon, France, 14-18 September 1998. Vienna, 1999. Proceedings series, ISSN 0074-1884. STI/PUB/1042. ISBN 92-0-101499-6.

IAEA, 1998b. International Atomic Energy Agency. *Radiological Conditions at Bikini Atoll: Prospects for Resettlement, Radiological Assessment Reports*. IAEA, Vienna (1998).

IAEA, 1998c. International Atomic Energy Agency. *The Radiological Situation at the Atolls of Mururoa and Fangataufa: Main Report*, Radiological Assessments Reports, IAEA, Vienna (1998).

IAEA, 1999d. International Atomic Energy Agency. *Radiological Conditions at the Semipalatinsk Test Site, Kazakhstan: Preliminary Assessment and Recommendations for Further Study*. Radiological Assessment Reports, IAEA, Vienna (1999).

IAEA, 1999f. International Atomic Energy Agency. *Radiological Conditions of the Western Kara Sea: Assessment of the Radiological Impact of the Dumping of Radioactive Waste in the Arctic Seas*. Radiological Assessment Reports, IAEA, Vienna (1999).

IAEA, 2000a. International Atomic Energy Agency. *Restoration of Environments with Radioactive Residues* (Proc. Int. Symp. Arlington, 1999), IAEA, Vienna (2000).

IAEA, 2000b. International Atomic Energy Agency. *Safety of Radioactive Waste Management*. Proceedings of an International Conference organized by the International Atomic Energy Agency et al in Cordoba, Spain, 13-17 March 2000. Proceeding series.ISSN 0074-1884, STI/PUB/1094, ISBN 92-0-101700-6. International Atomic Energy Agency, Vienna (2000)

IAEA, 2000c. International Atomic Energy Agency. Regulatory control of radioactive discharges to the environment. WS-G-2.3. Vienna: IAEA Safety Standards Series; 2000.

IAEA, 2001a. International Atomic Energy Agency. *National Regulatory Authorities with Competence in the Safety of Radiation Sources and the Security of Radioactive Materials*. Proceedings of an International Conference held in Buenos Aires, Argentina, 11–15 December 2000. IAEA, Vienna ,August 2001. IAEA-CSP-9/P. ISSN 1563–0153

IAEA, 2001b. International Atomic Energy Agency. *International Conference Chernobyl: Looking Back to go Forward.* Vienna: IAEA, 2001.

IAEA, 2001c. International Atomic Energy Agency. *Radiological protection of patients in diagnostic and interventional radiology, nuclear medicine and radiotherapy*. Proceedings of an international conference held in Malaga, Spain, 26–30 March 2001 / organized by the International Atomic Energy Agency...[et al.]. Vienna, 2001. Proceedings series, ISSN 0074–1884. STI/PUB/1113. ISBN 92–0–101401–5.

IAEA, 2001d. International Atomic Energy Agency, An International Peer Review of the Biosphere Modelling Programme of the US Department of Energy's Yucca Mountain Site Characterization Project, Report of the IAEA International Team, IAEA,Vienna (2001).

IAEA, 2002. International Atomic Energy Agency. *Appraisal for the United Kingdom of the safety of the transport of radioactive material*. IAEA Safety Standards Application—Trans SAS-3. Vienna: IAEA; 2002.

IAEA, 2003a. International Atomic Energy Agency. *Security of radioactive sources*. Proceedings of an international conference held in Vienna, Austria, 10–13 March 2003 / organized by the International Atomic Energy Agency…[et al.] Vienna. Proceedings series, ISSN 0074–1884. STI/PUB/1165. ISBN 92–0–107403–4.

IAEA, 2003b. International Atomic Energy Agency. *Safe decommissioning for nuclear activities*. Proceedings of an International Conference on Safe Decommissioning for Nuclear Activities / organized by the International Atomic Energy Agency and hosted by the Government of Germany through the Bundesamt für Strahlenschutz and held in Berlin, 14–18 October 2002. Vienna, 2003. Proceedings series, ISSN 0074-1884). STI/PUB/1154. ISBN 92-0-109703-4.

IAEA, 2003c. International Atomic Energy Agency. *Occupational radiation protection: protecting workers against exposure to ionizing radiation*. Proceedings of an International Conference on Occupational Radiation Protection: Protecting Workers against Exposure to Ionizing Radiation / organized by the International Atomic Energy Agency … [et al] and held in Geneva, 26–30 August 2002. Vienna, 2003. Proceedings series, ISSN 0074–1884. STI/PUB/1145. ISBN–92–0–105603–6.

IAEA, 2003d. International Atomic Energy Agency. *Safety of transport of radioactive material*. Proceedings of an International Conference on the Safety of Transport of Radioactive Material / organized by the International Atomic Energy Agency, co-sponsored by the International Civil Aviation Organization … [et al.], and held in Vienna, 7–11 July 2003. Vienna, 2003. Proceedings series, ISSN 0074–1884. STI/PUB/1200. ISBN 92–0–108504–4.

IAEA, 2003f. International Atomic Energy Agency. *Issues and trends in radioactive waste management.* Proceedings of an International Conference on Issues and Trends in Radioactive Waste Management / organized by the International Atomic Energy Agency in co-operation with the European Commission and the OECD Nuclear Energy Agency, hosted by the IAEA and held in Vienna, 9–13 December 2002. Vienna, 2003. Proceedings series, ISSN 0074–1884. STI/PUB/1175. ISBN 92–0–113103–8.

IAEA, 2004a. International Atomic Energy Agency. *Code of conduct on the safety and security of radioactive sources*. IAEA/CODEOC/2004. IAEA, VIENNA, 2004.

IAEA, 2004b. International Atomic Energy Agency. *Protection of the environment from the effects of ionizing radiation*. Proceedings of an international conference, Stockholm, 6–10 October 2003. — Vienna, 2004. Proceedings series, ISSN 0074–1884. STI/PUB/1229. ISBN 92–0–104805–X.

IAEA, 2004c. International Atomic Energy Agency. National infrastructures for radiation safety: towards effective and sustainable systems : proceedings of an International Conference organized by the International Atomic Energy Agency in cooperation with the World Health Organization … [et al.], hosted by the Government of Morocco through the University Mohammed V, Agdal and held in Rabat, 1–5 September 2003. IAEA, Vienna, 2004. Proceedings series, ISSN 0074-1884. STI/PUB/1193. ISBN 92-0-105404-1

ICRP, 1983. International Commission on Radiological Protection. *Cost-Benefit Analysis in the Optimization of Radiation Protection*. ICRP Publication 37. Ann. ICRP 10 (2-3).

ICRP, 1991. International Commission on Radiological Protection. *1990 Recommendations of the International Commission on Radiological Protection*. ICRP Publication 60; Ann. ICRP 21 (1–3).

ICRP, 1999. International Commission on Radiological Protection. *Protection of the public in situations of prolonged radiation exposure*. ICRP Publication 82; Ann. ICRP 29 (1–2).

ICRP, 2003. International Commission on Radiological Protection. *Biological effects after prenatal irradiation (embryo and foetus)*. ICRP Publication 90; Ann. ICRP 33 (1–2).

Kuhn, 1960. Thomas S. Kuhn. *The Structure of Scientific Revolutions*, p. 93, 1960.

Land, 2002. Charles E Land; *Uncertainty, low-dose extrapolation and the threshold hypothesis*; J. Radiol. Prot. 22 (2002) 1–7

Lindell, 1973. Bo Lindell. *Radiation and Man*. The 1973 Sievert Lecture. IRPA 3: Washington, September 1973.

Mettler, 2004. Fred A. Mettler, Jr. *Medical perspective on ways to improve radiation protection standards*. Health Phys 87:289 –292; 2004

NCRP, 1997. National Council on Radiation Protection and Measurements. *Uncertainties in Fatal Cancer Risk Estimates used in Radiation Protection*. NCRP Report 126, Bethesda,MD, 1997

Penrose, 1994. Roger Penrose, *Shadows of the Mind: A Search for the Missing Science of Consciousness*. ISBN 0-19-853978-9, 1994.

Preston et all, 2003. Dale L. Preston, Yukiko Shimizu, Donald A. Pierce, Akihiko Suyama, and Kiyohiko Mabuchi, *Studies of Mortality of Atomic Bomb Survivors. Report 13: Solid Cancer and Noncancer Disease Mortality: 1950–1997*. Radiat Res 160:381-407, 2003.

UNSCEAR 2000. *Sources and Effects of Ionizing Radiation, Volume I: Sources and Volume II: Effects* United Nations Scientific Committee on the Effects of Atomic Radiation. 2000 UNSCEAR Report to the General Assembly, with Scientific Annex (United Nations publication, Sales Nos. E.00.IX.3 and 4).

UNSCEAR, 2001. *Hereditary Effects of Radiation*. United Nations Scientific Committee on the Effects of Atomic Radiation. 2001 UNSCEAR Report to the General Assembly, with Scientific Annex (United Nations publication, Sales No. E.01.IX.2).