http://dx.doi.org/10.5516/NET.08.2014.714

CLARIFYING THE PARADIGM ON RADIATION EFFECTS & SAFETY MANAGEMENT: UNSCEAR REPORT ON ATTRIBUTION OF EFFECTS AND INFERENCE OF RISKS

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Received July 03, 2014

The aim of this paper is to describe a relatively recent international agreement on the widely debated concepts of: (i) attributing effects to low dose radiation exposure situations that have occurred in the past and, (ii) inferring radiation risk to situations that are planned to occur in the future.

An important global consensus has been recently achieved on these fundamental issues at the level of the highest international intergovernmental body: the General Assembly of the United Nations. The General Assembly has welcomed with appreciation a scientific report on attributing health effects to radiation exposure and inferring risks that had been prepared the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) following a formal request by the General Assembly.

KEYWORDS : Radiation Effects, Radiation Risks, Effect Attribution, Risk Inference, Safety Management, UNSCEAR, Radiation Paradigm

1. EPISTEMOLOGICAL BACKGROUND

Before the political consensus described in this paper was achieved, the epistemology on radiation risks and effects of low radiation dose exposure situations had been amply discussed in the peer reviewed literature (González, 2011). Such epistemology relates to the theories of knowledge applied for attributing the effects to and inferring the risks from radiation exposure situations, especially with regard to the methods, validity and scope of such theories. The attribution of radiation effects is a retrospective notion based on the concept of *provability*, which involves demonstrability, counterfactuality, and finally, the attestability that effects have actually been incurred in past exposure situations. The inference of radiation risk as a prospective notion is associated with the concept of probability, usually a Bayesian probability that quantifies risk in prospective exposure situations on the bases of radiobiological knowledge and epidemiological experience at high doses, usually expressed as a frequentistic probability. I had concluded that under present knowledge, radiation risks are inferable for prospective low-dose radiation exposure situations, however small the expected doses may be, and, therefore, that ascribing nominal radiation risks to planned exposure situations for radiation protection purposes is required for reasons of duty, responsibility, prudence and precaution. However, it was also concluded that the prospective attribution of radiation risk does not imply that actual effects can be automatically attributed retrospectively to low-dose exposure situations.

In fact *attribution* refers to the knowledge required for assigning health outcomes to past radiation exposure situations, namely for connecting radiation effects to precedent radiation exposure situations (and therefore assigning them unequivocally to the situation). This is different than the aptitude for inferring radiation risks to planned prospective radiation exposure situations. In this respect, the epistemology of attribution is associated, respectively, with the subtly distinct concepts of *probability* and *provability*, expressed with these cuasi-homonymous terms that cause much misunderstanding. They derive from a common root, the Latin *probare*, which means both 'to test' and 'to demonstrate'. This akin terminology is a recipe for confusion, and therefore requires an adequate semantics for conveying the concepts associated with radiation hazards.

Probability describes how plausible it would be that a planned radiation exposure be hazardous; quantitatively, it can measure *risk*. In fact, probability is the mean for quantifying the prospective inference of radiation risks. If previous statistical information on the effect occurrence is available, such probability can be derived frequentistically,

namely as the limit of the relative frequency of the effect occurrence in a large number of cases. If only indirect information on the plausibility of effect occurrence is available, evidential probability can still be estimated as a 'Bayesian' inference through experts' judgement. This is usually the case for prospective planned exposure situations at low doses, for which frequentistic data does not exist.

Distinctly, provability describes the capability to demonstrate retrospectively and by evidence the actual occurrence of radiation effects. While probability is restricted to quantifying the prospective plausibility of hazardous outcomes, provability aims at demonstrating the genuineness and validity of the causality of radiation effects, and therefore it is a precondition for attesting the existence of such effects unequivocally and unambiguously. Namely, if radiation effects are retrospectively provable, and their occurrence has been proved, then actual effects can be attributed to the past radiation exposure situation. Provability is the means for retrospectively revealing the occurrence of radiation effects.

It should be noted, however surprising it may be, that provability has not the quantifiable qualities of probability. Paraphrasing previous thinking in this area of epistemology (Gödel 1931), neither provable should be taken as a synonym of true, nor non-improvable as a synonym of false; rather, provability should be taken as a means for allowing qualified professionals to attest revealed effects with a high degree of confidence.

A final (and important clarification): Attribution should not be considered as a synonym of the legal term *imputation*, which is mainly linked to the concept of causation and its analogue causality. While attributing means regarding something (e.g. health effects) as being caused by something else (e.g. radiation exposure), diversely, imputing means ascribing *someone* (e.g., a nuclear employer) to be the cause of something bad (e.g., causing by imprudence radiation effects to an occupationally exposed worker). Imputation is mainly related to occupational compensation claims, for example, as part of a multi-stage test for legal liability associated with the causal relationship between the conduct of employers of occupationally exposed workers and the occupational harm that those workers may have experienced. These legal issues will not be discussed in this paper, but they have been internationally considered recently (ILO, 2010).

The UNSCEAR reported consensus on the above described concepts should have an enormous influence on the way that regulatory authorities consider radiation effects and their consequent safety management in the future.

2. RELEVANT RESOLUTIONS OF THE GENERAL ASSEMBLY OF THE UNITED NATIONS

In resolution 62/100 of 17 December 2007, the General Assembly had already encouraged UNSCEAR to submit a report to further clarify the assessment of potential harm owing to chronic low-level exposures among large populations and also the attributability of health effects at its earliest convenience (UN, 2007a)

Furthermore, the General Assembly, in resolution 63/89, endorsed UNSCEAR's strategy during the period 2009-2013 to increase awareness and deepen understanding among authorities, the scientific community and civil society with regard to levels of ionizing radiation and the related health and environmental effects as a sound basis for informed decision-making on radiation-related issues. Such a strategic objective 'highlighted the need for UNSCEAR to provide information on the strengths and limitations of its evaluations, which are often not fully appreciated. This involves avoiding unjustified causal associations (false positives) as well as unjustified dismissal of real health effects (false negatives). Specifically, there was a need to clarify the degree to which health effects could be attributed to radiation exposure' (UN, 2010).

In resolution 66/70, the General Assembly called upon UNSCEAR to submit, at its sixty-seventh session, the report requested by it on the attributability of health effects from radiation exposure (UN, 2011).

As a result of these developments, on 18 December 2012, the General Assembly of the United Nations, during its sixty-seventh session and under Agenda item 50, adopted its Resolution 67/112 on *Effects of Atomic Radiation* (UN, 2012). In this Resolution, the General Assembly *inter alia* 'is concerned about the potentially harmful effects on present and future generations resulting from the levels of radiation to which mankind and the environment are exposed'; 'commends the United Nations Scientific Committee on the Effects of Atomic Radiation for the valuable contribution it has been making since its inception to wider knowledge and understanding of the levels, effects and risks of ionizing radiation, and for fulfilling its original mandate with scientific authority and independence of judgment' and; significantly and importantly, '***welcomes with appreciation the scientific report on attributing health effects to radiation exposure and inferring risks***' that had been requested by the General Assembly in its resolution 62/100 of 17 December 2007 (UN, 2007b).

3. REPORTING FROM THE UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION

In its fifty-ninth session on 21-25 May 2012 UNSCEAR approved its customary report to the General Assembly (UNSCEAR, 2012). In this report, UNSCEAR informs the General Assembly that it discussed substantive documents on the attribution of health effects to different levels of exposure to ionizing radiation and on uncertainties in risk estimates for cancer due to exposure to ionizing radiation, and summarizes its findings with the support

of detailed scientific annexes that underpin them, which will be published separately (it is in print).

UNSCEAR addressed the attribution of health effects to different levels of exposure to ionizing radiation, and has reached a number of conclusions that are quoted in bold italics hereinafter and subsequently commented on by the author of this paper.

3.1 Attribution of Deterministic Effects

'An observed health effect in an individual could be unequivocally attributed to radiation exposure if the individual were to experience tissue reactions (often referred to as "deterministic" effects), and if differential pathological diagnoses were achievable that eliminated possible alternative causes. Such deterministic effects are experienced as a result of high acute absorbed doses (i.e. about one gray or more), such as might arise following exposures in accidents or in radiotherapy'

It is well known that large radiation doses may cause a substantial amount of cell death, sufficient to counterbalance the replenishing mechanisms and result in detectable tissue reactions. These reactions usually manifest a short time after irradiation, but can also occur later, causing observable harm to the organ or tissue, eventually to the individual, and, in extreme cases, resulting in death. In order to reach the level of diagnosis, a given proportion of cells must be depleted. These types of effects used to be termed 'deterministic' because they were all assumed to occur at doses in excess of a 'threshold' dose that could produce the necessary number of depleted cells. At present, they are preferably termed 'tissue reaction effects' because they present as a response of the affected tissues, and for some of them, the existence of a threshold dose is not evident. Tissue reactions occur after a threshold dose that is higher than what is normally termed 'low-dose'.

The main characteristic of these tissue reactions is that they are diagnosable in the exposed individual by an experienced radio-pathologist. They can therefore be assigned to the exposure situation and are thus attributable to the situation. The only condition for attributability is the achievement of differential pathological diagnoses that eliminated possible alternative causes.

3.2 Attribution of Stochastic Effects

'Other health effects in an individual that are known to be associated with radiation exposure — such as radiation-inducible malignancies (so-called "stochastic" effects) — cannot be unequivocally attributed to radiation exposure, because radiation exposure is not their only possible cause and there are at present no generally available biomarkers that are specific to radiation exposure. Thus, unequivocal differential pathological diagnosis is not possible in this case. Only if the spontaneous incidence of a particular type of stochastic effect were low and the radiosensitivity for an effect of that type were high (as is the case with some thyroid cancers in children) would it be plausible to the attribution of an effect in a particular individual to radiation exposurebe plausible, particularly if that exposure were high. But even then, the effect in an individual cannot be attributed unequivocally to radiation exposure, owing to competing possible causes'.

It is also well know that if cells are not killed by radiation but remain viable, and with genetic information modified by radiation exposure, such modifications may be transmitted to daughter cells. Mutations in single cells may eventually lead to serious consequences. If the mutations occur in somatic cells and involve modifications in genes related to the formation or prevention of malignancies, certain types of cancers may develop in the tissue or organs of the exposed individual. If mutations occur in germ cells, namely those concerned with transmitting genetic information to the descendants of the exposed individual, it is possible to think that hereditary disorders may arise. These types of effects in the individuals or in their descendants are latent, in the sense that they may manifest a long time after the exposure. They are aleatory, occurring at random, and are therefore termed 'stochastic'.

A main characteristic of stochastic effects is that it is not feasible to associate radiation exposure with a particular individual affected by an effect. The reason is that until now there is no biomarker that shows such association.

The demonstrability of stochastic effects can be therefore done only collectively, e.g. demonstrating the increase of the prevalence of such effects on a large exposed population. Demonstrability implies that the effect occurrence is clearly apparent and even obvious, i.e. capable of being logically revealed by showing the steps taken to create an argument of occurrence. Conversely, if the occurrence becomes indemonstrable, it can be concluded that it is axiomatic; namely it might seemingly be obvious and manifest, a proposition regarded as being self-evidently true, but is not able to be proved.

The demonstrability that radiation effects have actually occurred includes the following situations:

- Situations where the occurrence of the effects is clearly verifiable, such as the situations leading to tissue reactions discussed before, or situations such as those of the survivors of the Hiroshima and Nagasaki nuclear bombings, where a clear increase in the prevalence of some cancers is epidemiologically evident. In these situations the effect occurrence is verifiable when it can be logically established with confirmable steps in an argument of occurrence.
- Situations where the occurrence of the effects is ostensible: when it is apparently but not necessarily true. Attribution can be ostensible when the 'background' incidence of the effect is low, and the radiosensitivity of the effect is high. A typical case of ostensibility is attributing paediatric follicular thyroid cancer in children exposed to radio-iodine.

- Situations where the occurrence is axiomatic, which is applicable to all other situations of radiation exposure, namely it is just a preposition regarded as being self-evidently true but not able to be demonstrated.

In sum, stochastic effects can be verifiable only collectively rather than individually. They can be verifiable through epidemiological studies as prevalence over the exposed population. In some circumstances, individual radiation effects cannot be demonstrated (and therefore attested) but they can nevertheless be ostensible, i.e. apparently true, but not necessarily so.

It shall be emphasized that for all individual cases, the occurrence of stochastic effects is axiomatic for reasons of *contrafactuality*. Contrafactuality is the distinguishing attribute of being contrary to being actual or based on fact, (usually as a hypothesis). The analysis of contrafactuality between radiation exposure and its effects is essential to assess whether the effects are provable at an individual level. In this regard, the concept of a subjunctive conditional declaration (sometimes also termed remote conditional declaration) on the facts connecting radiation exposure and its effects on an individual is particularly important. This type of declaration, which is usually termed *counterfactual conditional*, is particularly relevant to understand the logical links between radiation exposure and health effects.

The crucial question governing the counterfactuality of radiation effects can be formulated as follows: Can the premise '*health effects have been incurred by an individual following radiation exposure*' be explained in terms of a counterfactual conditional declaration of the form '*should the radiation exposure not have occurred, would the health effects not have been incurred*?' The answer to this critical question is decisively negative for stochastic effects. In fact, if cancer develops in a given individual following a given radiation exposure, it cannot be affirmed with certainty that should the radiation exposure have not occurred, the cancer would not have occurred, because such cancer could have originated by a different cause.

3.3 Epistemological Limitations of Radio-epidemiology

'An increased incidence of stochastic effects in a population could be attributed to radiation exposure through epidemiological analysis — provided that, inter alia, the increased incidence of cases of the stochastic effect were sufficient to overcome the inherent statistical uncertainties. In this case, an increase in the incidence of stochastic effects in the exposed population could be properly verified and attributed to exposure. If the spontaneous incidence of the effect in a population were low and the radiosensitivity for the relevant stochastic effect were high, an increase in the incidence of stochastic effects could at least be related to radiation, even when the number of cases was small'

The constraints imposed by the demonstrability and contrafactuality of the effect occurrence impose a de facto epistemological threshold on their provability. For stochastic effects, the epistemological constraints are dominated by epidemiological uncertainties. Estimates of stochastic effects are by definition indecisive, i.e. uncertain, particularly at low doses. Uncertainty is a descriptor and quantifier of the epistemological limits of the estimations. It is the concept used to qualify what is not known, reliable or definite and when science is not completely confident or sure. Two types of uncertainties are usually recognized: *aleatory*, which are due to the stochastic variation of the magnitudes of the estimates; and *epistemic*, which are those due to lack of knowledge founded on an incomplete characterisation, understanding or measurement of the system describing radiation effects. Uncertainties dominate the epistemology of the multiple phenomena linking radiation-induced DNA mutations with the expression of health effects. Knowledge is uncertain simply because many facts are ignored, the available information is not fully dependable, and therefore, the conclusions derived from such information may be doubtful. This is particularly the case when the radiation dose is low and delivered at low rates. The possible physiological mechanisms associated with protracted radiation health effects can be hypothesised, even inferred, but without complete confidence or assurance that the assumptions are correct.

UNSCEAR has identified a large number of sources of uncertainty in the epidemiological estimates of radiation effects, which cause de facto 'epistemological thresholds', namely limits in the theory of knowledge about stochastic effects. For reasons of simplicity, it would be sufficient to analyze one of the more dominant uncertainties and assess its influence on demonstrability. This is the aleatory uncertainty in the estimates, due to the impact of dose levels and the epidemiological sample size on statistical power.

There are many different types of radio-epidemiological studies, but they generally compare an exposed group of people against a similar but unexposed control group. In order to quantify the effect in the exposed group, the difference between the number of health effects in the exposed group (E) and those in the control group (C), E – C, must be determined. However, both, E and C, fluctuate statistically, usually following a normal distribution. Thus, in order to attest that effects have actually occurred, the difference E – C should be larger (by about twice) than its standard deviation, $\sqrt{E}$–C. Under this condition, the effects can be epidemiologically attested if, and only if, the radiation dose, D, is larger than the inverse square of the number of people in the epidemiological study, N, namely: $D > cN^{-2}$, where 'c' is a constant that depends inter alia on the background incidence of the health effects in question (Beninson, 1996). Thus, in a log D – log N coordinate plane, a straight line will demarcate the area where effects can be attestable through epidemiological studies, namely *provable*, from that where the actual occurrence of effects cannot be proved – however plausible

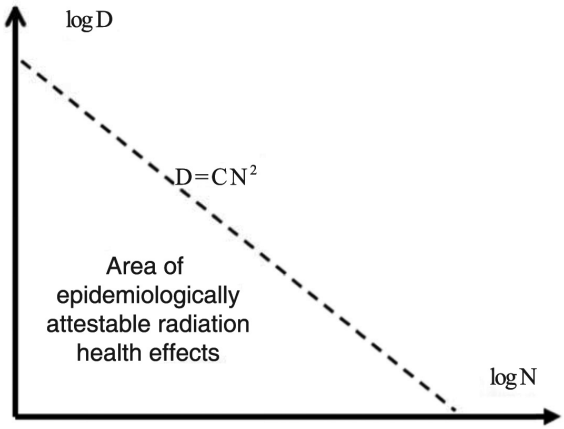

Fig. 1.

these effects might be. This is illustrated in the following figure, which presents the epistemological limitations for attesting to the occurrence of stochastic effects due to the aleatory uncertainty of the estimates, because of the impact of dose level (D) and the epidemiological sample size (N) on statistical power.

3.4 Attributability of Hereditary Effects

'Although demonstrated in animal studies, an increase in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure; one reason for this is the large fluctuation in the spontaneous incidence of these effects'

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 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
- 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).
- In sum, that for a population exposed to radiation in one generation only, the risk of hereditable effects to the progeny of the first postradiation generation should be inferred to be 3000–4700 cases per Gy per one million progeny, which constitutes 0.4–0.6% of the baseline incidence of those disorders in the human population.

But UNSCEAR now emphasizes that there is not any epidemiological evidence on such numbers. They are Bayesian probabilities assigned by taking into account the available biological information, but this cannot be used to attribute hereditary effects. Moreover, it is obvious that the estimated risk of 0.4–0.6% of the baseline incidence of those disorders would make it statistically impossible to attribute hereditary effects to any exposure situation.

3.5 Biological Indicators of Radiation Exposure vis-à-vis Attribution

'Specialized bioassay specimens (such as some haematological and cytogenetic samples) can be used as biological indicators of radiation exposure, even at very low levels of radiation exposure. However, the presence of such biological indicators in samples taken from an individual does not necessarily mean that the individual would experience health effects due to the exposure'.

There is ample evidence that radiation exposure triggers the presence of biological indicators such as cytogenetic samples of chromosomal aberrations. These indicators are very useful for confirming and quantifying radiation exposure of individuals. However, UNSCEAR emphasizes there is not necessarily a correlation between these indicators and health effects actually occurring.

3.6 Attributability of Health Effects to Radiation Levels Typical of the Global Average Background

'In general, increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of the global average background levels of radiation. This is because of the uncertainties associated with the assessment of risks at low doses, the current absence of radiation-specific biomarkers for health effects and the insufficient statistical power of epidemiological studies.'

From the epistemological limitations of epidemiology described before, it becomes clear that it is impossible to attribute effects at low radiation doses. The provability of collective effects of radiation doses typical of the global average background levels of radiation, namely of around several millisieverts per year, would require epidemiological studies involving cohorts of hundreds of thousands of people that would render the study unfeasible.

3.7 Wrong Estimations of Radiation-induced Health Effects

'Therefore, the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels.'

This is an extremely important conclusion because these theoretical calculations have done a lot of harm already. Unfortunately, radiation effects have been theoretically calculated retrospectively by using risk estimates,

specifically the nominal risk coefficients recommended by the International Commission on Radiological Protection (ICRP) for radiation protection purposes, which in turn are based on UNSCEAR estimates. The relative risk of stochastic effects has been estimated by UNSCEAR on the basis of available radio-epidemiological studies in humans exposed to relatively high radiation doses (UNSCEAR, 2009). The extrapolated excess lifetime mortality (averaged over both sexes) is:

- for all solid cancers combined 3.6–7.7% per Sv for an acute dose of 0.1 Sv, and 4.3–7.2% per Sv for an acute dose of 1 Sv
- for leukaemia 0.3–0.5% per Sv for an acute dose of 0.1 Sv, and 0.6–1.0% per Sv for an acute dose of 1 Sv.

Taking into account the UNSCEAR risk estimates and its own findings, the ICRP recommended the use of 'detriment-adjusted nominal risk coefficients' only for the purpose of radiological protection (ICRP, 2007). These coefficients are numerals expressed in % per unit dose, which – multiplied by dose – aim at quantifying the plausibility or 'degree of believe' of latent effects as a late outcome of radiation exposure. They are nominal, in the sense that they do not necessarily correspond to a real value, since they relate to theoretical calculations using hypothetical (not real) people who are averaged over age and sex. Since the different possible effects may cause distinct detriment to people, the coefficients are multidimensional, quantifying the plausible expectation of harm, and including inter alia the weighted plausibility of fatal and non-fatal harm, and life-lost should the harm actually occur. Following a number of paradigmatic sequential steps, ICRP calculated and recommended detriment-adjusted nominal risk coefficients as follows (ICRP, 2007):

- for malignancies:
  - 5.5% Sv^{-1} for a whole population
  - 4.1% Sv^{-1} for an adult population.
- for hereditable effects:
  - 0.2% Sv^{-1} for a whole population
  - 0.1% Sv^{-1} for an adult population,

which results in a combined value of

- 5.7% Sv^{-1} for a whole population
- 4.2% Sv^{-1} for an adult population.

International radiation safety standards have taken the UNSCEAR estimates and ICRP recommendations into account, with a rounded overall nominal risk coefficient of ~5% Sv^{-1}. This approach forms the basis of the international requirements for protecting people against radiation in planned exposure situations (IAEA, 1996; IAEA, 2011) but not for assessing dead bodies. However, these nominal coefficients have been used in mathematical calculations and the result then assumed to be equal to proven effects and attributed to the exposure situation. The calculation is extremely simplistic: the collective dose of the exposure situation is theoretically assessed and then multiplied by the nominal risk coefficient. The unit of the result of this operation is 'persons' (person-dose × % dose–1) and it is automatically equated to the number of effects (usually as dead people).

These computations of dead bodies so attributed to radiation exposure situations have flourished since the Chernobyl accident. Serious international organizations, such as the IAEA, WHO and the UNDP have fallen in that mathematical trap. On 5 September 2005, they issued a press release on the finalization of the so-called Chernobyl Forum. Under the title *Chernobyl: The True Scale of the Accident – 20 Years Later a UN Report Provides Definitive Answers and Ways to Repair Lives*, the release reports that 'A total of up to four thousand people could eventually die of radiation exposure from the Chernobyl nuclear power plant (NPP) accident nearly 20 years ago, an international team of more than 100 scientists has concluded'. The connotation for the public was that 4000 individuals have been confirmed to be killed in Chernobyl. After a few months, on 25 March 2006, *the Guardian* of London published the following headline: '*UN ignores 500,000 Chernobyl deaths: IAEA says will be less than 4000*', reporting on the same theoretical calculations with different assumptions. Even respected academies fall into the trap. The New York Academy of Sciences published the book '*Chernobyl: Consequences of the Catastrophe for People and the Environment*', which concludes that based on records now available, some 985,000 people died of cancer caused by the Chernobyl accident (Yablokov et al., 2009). Following the Fukushima accident in Japan a similar pattern has occurred.

Specialists have been dealing with this conundrum somewhat ambiguously, basically stating that such a theoretical calculation cannot be done. But many people asked themselves, why not? Why cannot the product of collective dose and nominal risk coefficients be equated to the number of attributable deaths to an exposure situation? The dilemma confronted by specialists was how to respond unambiguously to the following question: if the risk of 5% per Sv is not real, then: Why are radiation protection standards needed? Conversely, if the 5% per Sv is real, then: Why is attributing real fatalities to radiation exposure wrong?

The new UNSCEAR report brings an ultimate answer to this dilemma. The thesis implicitly demonstrated by the report is that:

- RISKS of health effects can be prospectively inferred to planned radiation exposure situations for purposes of radiation protection, but
- ACTUAL HEALTH EFFECTS cannot generally be attributed to radiation exposure situations just on the basis of those risks and, therefore, actual fatalities cannot be assigned on that basis to radiation exposure situations.

3.8 Inference of Radiation Risk

'The Scientific Committee notes that public health bodies need to allocate resources appropriately, and that this may involve making projections of numbers of health effects for comparative purposes. This method, though based upon reasonable but untestable assumptions, could be useful for such purposes provided that it were applied consistently, the uncertainties in the assessments were taken fully into account, and it were not inferred that the projected health effects were other than notional.'

This is a final and important conclusion: the fact that health effects cannot be attributed to low radiation doses does not mean that radiation risk cannot and should not be prospectively inferred for radiation protection purposes in planned exposure situations at low doses.

ICRP had deeply analyzed the issue of radiation risk at low levels (ICRP, 2006), and concluded that while the existence of a low-dose threshold of risk does not seem to be unlikely for radiation-related cancers of certain tissues, the evidence does not favour the existence of a universal threshold. On the basis of studies of uncertainty, low-dose extrapolation and the threshold hypothesis, and by using techniques of quantitative uncertainty, ICRP analyzed the consequences of allowing for the uncertain possibility of a risk threshold. By this approach of *reductio ad absurdum*, the ICRP concluded that the uncertain possibility of a threshold does not drastically reduce either central estimates or upper probability limits for low dose risk compared with those obtained using the LNT model, unless the possibility of a threshold is very high. This important conclusion was reached by analysing the implications of a possible, but uncertain, low-dose threshold, which are summarised by the dependence of the mean value and the upper 95% probability limit on the presumed threshold probability value. The following figure illustrates the mean and upper 95% probability limit for Excess Relative Risk (ERR) per Gy as functions of threshold probability p, given (in the absence of a threshold) a lognormal uncertainty distribution with a mean of 0.17 and an upper 95% limit of 0.36.

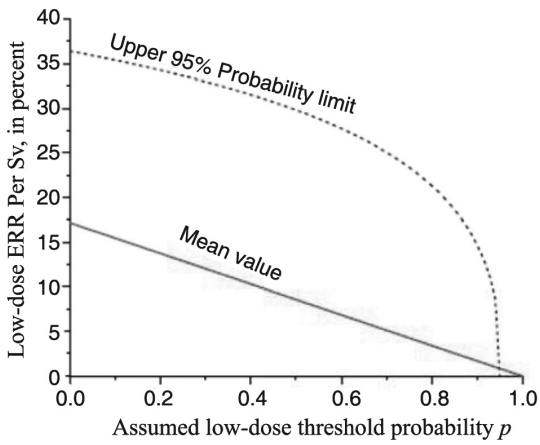

Fig. 2.

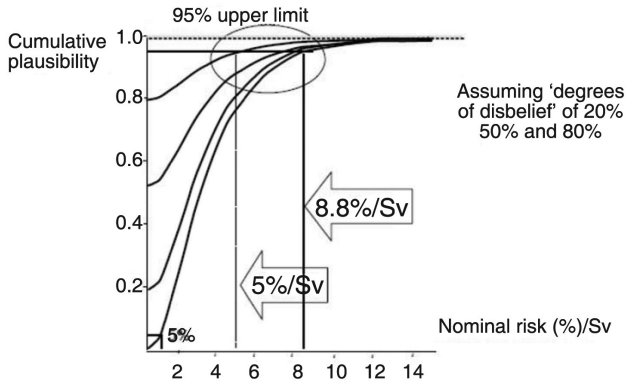

Fig. 3.

The mean value of estimated ERR per Gy is proportional to (1 – P) for the known threshold probability P and is proportional to (1 – E(p)) for an uncertain threshold probability p with the expected value E(p). The effect on the upper 95% probability limit is less drastic, unless the assumed probability of a threshold is high. As shown in the above figure, the upper limit decreases with increasing P, but not nearly as steeply as for the mean until P approaches the probability level of the upper limit: for example about 0.85 in the case of a 95% limit. Obviously, the lower 95% limit (the 5th percentile of the distribution) is zero for $P \geq 0.05$.

The following figure illustrates different 'degrees of belief (or disbelief)' on a risk threshold applied to the cumulative distribution of probability, converting it into a cumulative distribution of plausibility. It can be seen that the plausible upper boundary for a threshold of 8%/Sv changes very little as the disbelief increases. For a large disbelief, as high as 80%, the upper bound is 5%/Sv, i.e. equal to the nominal risk coefficient used in international radiation protection standards.

In sum, taking into account the available objective evidence, a nominal risk coefficient of around 5% per Sv seems to be an unavoidably prudent consideration for radiation protection purposes. Moreover, other subjective qualifiers will lead to the same conclusion; these include consideration of verisimilitude, believability, logicalness, admissibility, fidelity and integrity, and the related concept of falsifiability.

4. EPILOGUE

The highest international intergovernmental body has reported the international consensus of the vastly debated issue of health effects derived from exposure situations. Such a consensus serves to ratify what was already an agreement in most scientific fora. Namely:

- The attribution of radiation health effects should always be retrospective rather than prospective; conversely, radiation risk can be prospectively inferred.
- Deterministic health effects are individually attributable to exposure situations involving high doses.
- Stochastic effects of radiation-induced cancers are collectively (not individually) attributable, and only in the case that radiation doses are sufficiently high as to permit epidemiological discernment.
- Stochastic effects of radiation-induced cancers are not attributable to radiation exposure situations involving radiation doses similar to typical of the global average background levels.
- Stochastic hereditary effects are not attributable to any radiation exposure situation.
- The presence of biological indicators of radiation exposure is not synonym of radiation effects.
- The calculation of prospective radiation effects multiplying collective doses by nominal risk factors is wrong.
- Radiation risk from planned situations can and should prospectively be inferred, but only for purposes of radiation protection and allocation of resources.

The time is now ripe for regulatory authorities to convert this international consensus into commensurate instruments for regulating radiation exposure.

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