Why Low-level Radiation Exposure Should Not Be Feared

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***Abstract*—The purpose of this paper is to address the public fear that is usually associated with low-level radiation exposure situations. Its ultimate objective is to provide persuasive assurances to informed but skeptical members of the public that exposure situations involving low-level radiation are not to be feared. Unfortunately, just acquiescing to an unsupportive public fear of low-level radiation is not without consequences. It is causing severe disruptions to the benefits that harnessed radiation can produce for the well-being of all humanity. In this pursuit, the paper provides the scientific and epistemological basis needed for regulatory reform by reviewing the history in quantifying, understanding, modeling, and controlling radiation exposure, including some of the evolving contributions of the United Nations Scientific Committee on the Effects of Atomic Radiation, the International Commission on Radiological Protection, and the myriad of international and intergovernmental organizations establishing radiation safety standards. It also explores the various interpretations of the linear no-threshold model and the insights gained from radiation pathologists, radiation epidemiologists, radiation biologists, and radiation protectionists. Given that the linear no-threshold model is so deeply imbedded in current radiation exposure guidance, despite the lack of a solid scientific base on the actually proven radiation effects at low-doses, the paper suggests near-term ways to improve regulatory implementation and better serve the public by excluding and/or exempting trivial low-dose situations from the regulatory scope. Several examples are given where the unsubstantiated public fear of low-level radiation has resulted in crippling the beneficial effects that controlled radiation offers to a modern society.**

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INTRODUCTION

IF PROPERLY harnessed, ionizing radiation (or radiation, in short) has yielded extraordinary benefits in the world of medicine, agriculture, and general industry. If left uncontrolled, however, high levels of radiation exposure can lead to severe health effects. But this does not justify fearing situations involving low levels of radiation exposure. This dichotomy is usual to many human endeavors. We protect ourselves against high levels of harmful agents, but on the other hand, we live in harmony and are unconcerned with lower levels of the same agents.

However, experience has shown that unpleasant emotions are often caused within the public at large and in their representatives by the mere mention of the word "radiation." There appears to be a feeling of threat from radiation at any level—even down to very low levels of radiation exposure. In spite of early efforts to put radiation in perspective (Ander and Gonzalez 1989), this physical phenomenon, which is strange for many people in spite of its naturalism (perhaps because they cannot touch, see, or smell it), has become the nemesis of many beneficial endeavors for society.

The purpose of this paper is to address the public fear that is usually associated with low-level radiation exposure situations. Its ultimate objective is providing persuasive assurances to informed but skeptical members of the public that exposure situations involving low-level radiation are not to be feared.

As such, we feel a key step is to provide scientific and epistemological arguments for persuading our colleagues in the radiation protection community and the regulators who receive their advice that the current situation has created a state of fear of low-level radiation exposure and that this could be causing more harm than benefit, violating a basic ethical principle of our profession. This might in turn provide steps for changing the way regulations are established and implemented. Such changes, properly communicated, should ease the fear that permeates a large segment of the general public.

Unfortunately, just acquiescing to an unsupportive public fear of low-level radiation is not without consequences. It is causing severe disruptions to the benefits that harnessed radiation can produce for the well-being of all humanity.

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QUANTIFYING RADIATION

Usually, physical phenomena affecting our lives are not quantified with such detail and controlled so conservatively as radiation exposure. In their efforts to provide such control, radiation health professionals have developed a rather elaborate but somewhat bewildering system based on a quantity that is confusedly termed [radiation] *dose*, which is understood by most people as a quantity of a medicine or drug taken at one time. But for radiation, such a dose expresses the amount of energy delivered by the emitted radiation to a unit mass of tissue. A challenge in definition arises because the human health effects of radiation exposure depend upon not only the dose incurred but also on the type of radiation (i.e., alpha, beta, gamma, etc.), the energy of the radiation, and the suspected sensitivity of the particular tissue being exposed.

To account for these variables, radiation is usually not controlled in terms of either the dose it delivers or the amount of radioactivity that generates such radiation. Rather, it is "measured" in terms of a non-physical entity that "weights" the physical dose. Stated differently, this physical radiation dose is modified by subjective weighting factors (i.e., factors that are conjectured rather than proven facts) that estimate the influence of the type of radiation involved in the exposure situation and the radiosensitivity of the different organs in the body being exposed. Such weighted dose is termed "effective dose," but usually it is simply called "dose."

It is to be noted that conventionally, the term "dose" is generally used to mean the amount of substance interacting with a target tissue. In radiobiology, dose means an amount of a "substance-equivalent" per unit mass. This translates into a ratio causing observed effects in the exposed system. In pharmacology, for instance, dose is a mass per body weight, whereas in radiation biology, dose is a weighted ratio of energy absorbed per exposed unit mass, which roughly expresses the weighted amount of the energy that different parts of the human body absorb from radiation exposure.

But differently than for other bodily attacks, it is not the dose incurred (i.e., the amount received in a given period of time or due to a particular action) that is assessed but rather the so-called "committed dose." This is the lifetime dose expected to be incurred as a result of an exposure. Moreover, control is not even exercised over such "committed dose" but rather over what is confusedly termed "dose commitment." This is defined as the total committed doses that would eventually result from any endeavor involving radiation exposure.

In the recent Congress of the International Radiation Protection Association (IRPA), a critique was presented including the potential difficulties with the system of radiation quantities and units—recognizing the confusion it generates even in professional audiences (Gonzalez 2021). Such radiation definition complexities are likely responsible for misunderstanding and even puzzlement among members of the public and are, therefore, partially responsible for the fear caused by radiation.

RADIATION HEALTH EFFECTS

As with other agents involved in our daily life, radiation is quantified and radiation exposure is controlled because of its potential health effects. The health effects of radiation have been meticulously studied for well over a century—with far more in-depth investigations than for any other known bodily attack.

In fact, the health effects of no other agent are studied and agreed upon at the highest international and intergovernmental level as is the case for radiation health effects. The international intergovernmental organization charged with the estimation of radiation health effects is the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), which reports its estimates annually to the United Nations General Assembly (UNGA) of the 194 countries that are members of the United Nations. UNSCEAR was established by the United Nations in 1955 with the mandate to assess and report levels and effects of exposure to ionizing radiation (UN 1955). Governments and organizations throughout the world rely on UNSCEAR´s estimates as the scientific basis for evaluating radiation risk and for establishing protective measures. No other agents affecting people have the benefit of a similar level of scientific support.

As a result, the radiation health effects that should be of concern for society are well known. It is undisputable that exposure to high levels of radiation dose, delivered at relatively high levels of changing dose rates, cause harmful acute effects to the human body. These health effects are observable and diagnosable in individuals exposed to such high doses and can be unequivocally attested by a radiation pathologist as being attributable to radiation exposure. The individuals exposed to such high doses experience tissue reactions (often referred to as "deterministic" effects, because above certain levels of dose, these effects are "determined" to occur) for which differential pathological diagnosis and attestation are achievable that eliminate possible alternative causes. The occurrence of such a deterministic effect is uncommon in practice. Some deterministic effects have been suffered by workers as a result of high radiation exposures in serious accidents; some others occurred in patients due to the erroneous administration of radiation dose in radiotherapeutic treatments and in interventional radiology. Radiation safety measures are undertaken to prevent such exposures and, as a result, such adverse effects are exceedingly rare, given the usual safety endeavors involving radiation exposure.

Below certain threshold high dose levels, such acute radiation health effects that can be diagnosed in individuals and attributed to the radiation exposure do not occur. However, at modestly high and medium dose levels, some delayed limited increases in the background incidence of other health effects have been observed, such as malignancies that have been associated with significant radiation exposure. These effects occur randomly and therefore are termed "stochastic" (from the Greek stokhastikós, "aim at, guess"), meaning having a random probability distribution or pattern that can be analyzed statistically in a cohort of exposed people. Potentially radiation-inducible malignancies are indistinguishable from generic background malignancies, which are rather common (around a quarter of the world population suffer a malignancy during their life), and therefore:

- They cannot be unequivocally attributed to radiation exposure in an exposed individual because radiation exposure is not the only possible cause of their occurrence; and
- Their incidence in a cohort of exposed people is extremely difficult to detect at medium doses and impossible to observe at low doses because of the presence of a high background incidence.

It should be noted that there are at present no biomarkers of malignancies that are specific to radiation exposure. Even if these biomarkers were discovered, they would most probably be unable to distinguish potential effects from human-made radiation exposures vis-à-vis background exposure, which is usually higher than that caused by human activities.

The presence of such "stochastic effects" has been identified throughout epidemiological studies of large cohorts of people who have incurred high and medium doses, delivered at relatively high and highly changing dose rates—notably the survivors of the nuclear bombing of the Japanese cities of Hiroshima and Nagasaki. Their incidence is relatively low, but it is statistically measurable if the cohort of exposed population is large and their radiation doses are relatively high.

In summary,

- Attribution of stochastic effects to exposure situations is not possible in individuals;
- Attribution is only achievable collectively for a large cohort exposed to relatively high doses, and it is usually expressed as an increase in the background incidence of the stochastic effects in that cohort; but
- Such collective attribution is <u>not</u> achievable for low-dose radiation exposure situations; namely, for those situations involving exposure levels typical of the global range of radiation background levels. (These levels are around those usually established as limits by regulatory authorities and in international standards.)

UNSCEAR has issued a report that recapitulates and clarifies the epistemology as well as the scientific knowledge for attributing observed health effects in individuals and populations to radiation exposure and distinguishes that from inferring conjectural risks (i.e., an educated guess, inferred from incomplete evidence) to individuals and populations from an exposure (UNSCEAR 2012a). It concluded that increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at such low levels. UNGA has endorsed this report (UN 2012).

Simply put, in the normal radiation exposure situations that are controlled by regulators, the occurrence of radiation health effects cannot be attested, either individually or collectively. "Risks" can be only subjectively inferred. Effects, if any, would be unobservable due to both epistemic and statistical limitations. Whereas there remains considerable controversy regarding the actual mechanistic biological responses to low-dose exposure, the ultimate effects on health (if any) and the subjectively inferred risk would be so small that there would be no reason to harbor any fear.

DEVELOPING THE RADIATION PROTECTION PARADIGM

The radiation protection paradigm, or model, used for controlling radiation exposure is globally accepted. Based on this paradigm, a unique international and intergovernmental system of radiation protection standards is being established in co-sponsorship by all relevant organizations within the United Nations system. A similar approach does not exist for any other agent affecting public safety.

Such international and intergovernmental focus-in-depth on radiation health effects, along with the associated development of a sophisticated system of safety standards, should have been a reason for reassuring the public that radiation is very well understood and properly controlled for public protection. Unfortunately, such an extensive focus—even on low radiation doses where no detrimental effects have ever been seen—may be having the opposite effect.

From a historical perspective, as soon as x rays and radioactivity were discovered by the end of the nineteenth century, the new professional communities of radiologists became aware of the detrimental effects of high-level radiation exposure. They realized the need for a paradigm or model for the protection of themselves. In 1928, a few decades after these discoveries, the International X-ray and Radium Protection Committee was created by the 1928 Second Congress of Radiology in Stockholm. This Committee would eventually evolve into today's International Commission on Radiological Protection (ICRP) (Lindell 1996; Clarke and Valentin 2008). ICRP is a non-governmental international charity that provides recommendations on radiation protection to professionals using radiation and to agencies responsible for regulating the use of radiation.

The ICRP activities generated the profession of radiation-protectionists. This is a large community of specialists who are internationally grouped under the IRPA. Their work is governed by three principles developed by the ICRP since the mid-1970s, which have since evolved into the currently recommended paradigm (ICRP 2007a). These are based on founded ethical doctrines (Gonzalez 2011a; ICRP

2018): namely, the justification of actions that result in changes of the radiation exposure situation; the optimization of radiation protection by selecting the best protection options under the prevailing circumstances; and the limitation of the committed individual doses. A fourth principle on protection of the future and the environment was implicit in ICRP recommendations, but it was specifically added by the intergovernmental international organizations and reads as follows: "People and the environment, present and future, must be protected against radiation risks" (IAEA 2006). This universal paradigm was elaborated over a number of years, becoming de facto universal around the 1990s (ICRP 1991). It is commensurate with the "precautionary principle" recommended by the United Nations Educational, Scientific and Cultural Organization (WC 2005).

The international and intergovernmental radiation safety standards based on the ICRP paradigm are established in collaboration with the European Commission (EC), the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Commission of Radiation Units and Measurements (ICRU), Unit of the International Labour Organization (ILO), the Organization for Economic Co-operation and Development Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP), and the World Health Organization (WHO), all under the aegis of the IAEA that issues the standards. The first standards were issued in 1962 (IAEA 1962). They were very much improved at the end of last century (IAEA 1996a), and they have been updated recently (IAEA 2014).

THE CURRENT PARADIGM

The ICRP paradigm is currently used worldwide. It implies a conservative assumption: that the proven risk of radiation at high doses can be conjectured for low doses as well, despite a lack of direct evidence supporting such a conjecture—and in spite of a UNSCEAR pronouncement that health effects at such low doses cannot be attributed (see last paragraph under "Radioepidemiologists" in the section titled "The Linear No-Threshold Regulatory Approach").

The ICRP purports to be aware that there are recognized exceptions to such an assumption embedded in their paradigm but still judges that for the purposes of radiation protection in the dose range below about 100 mSv, it is plausible to assume that the incidence of detrimental effects may rise in direct proportion to an increase in the dose in the relevant organs and tissues. Therefore, the paradigm recommended by the ICRP is based upon the assumption that at any dose, including doses below about 100 mSv, a given increment in dose will produce a directly proportionate increment in the risk (i.e., probability) of incurring effects attributable to radiation.

The ICRP paradigm was initially developed to be suitable for practical operational protection for occupational exposure situations where international legally binding obligations for labor may be involved (ILO 1980).

In ICRP's ongoing efforts to improve their guidance in response to increasing scientific input, a formal quantitative uncertainty analysis has been used to combine the uncertain components of estimating the chance of incurring radiation-related malignancies with and without allowing for the uncertain possibility of a universal low-dose threshold. Whereas the existence of such a low-dose threshold in the risk-dose relationship is not seen by ICRP as unlikely for radiation-related cancers of certain tissues (ICRP 2005), it concluded that the evidence does not favor the existence of a universal risk threshold. However, both UNSCEAR (UNSCEAR 2012a) and ICRP considered that such effects in this low-dose region be referred to as only notional effects.

On such basis, a so-called "detriment-adjusted nominal probability" per unit dose coefficient was developed by ICRP, the value being around 5% Sv^{-1} of dose. Thus, dose restrictions for radiation protection purposes are currently implicitly recommended on the basis of a risk coefficient of 0.005% mSv^{-1} (a thousandth of a Sievert is termed millisievert or mSv). It is to be noted that while 5% Sv^{-1} is mathematically equivalent to 0.005% mSv^{-1}, these two factors are epistemologically very different. The first is based on measured data and the second on conjectural experts' judgments.

It is crucial to emphasize this important difference. This paradigm is based on epidemiological factual data usually obtained from exposure situations involving high doses, high dose-rate, and in many cases large variations in the dose-rate change, and where an epidemic of attributable radiation effects is evident and scientifically quantifiable by professional radioepidemiologists. This could be done well with the cohort of the Hiroshima and Nagasaki bombing survivors and with the children around Chernobyl contaminated with high levels of radioiodine via milk ingestion, just to show two examples where an epidemic of radiation effects was suffered. For such whole-body radiation exposures, the probability of someone in the cohort developing an attributable malignancy is considered to be around 10^{-2} Sv^{-1} of effective dose incurred (based on no threshold but including variations with sex, conditions of exposure, etc.) (IAEA 2014; ICRP 2007a).

But a critique to this coefficient is that expressing it with the quantity effective dose and the unit Sievert is equivocal because this quantity and this unit were defined for low doses. An even more serious problem arises due to the scientific data being accumulated from situations where there was an epidemic of radiation effects being extrapolated to radiation exposure situations where there is no obvious epidemic, the doses are low, the dose rate is low, and the change in the dose rate is very low.

The paradigm then conjectures that factual epidemiological data supporting the risk of 10^{-2} Sv^{-1} are applicable to low-radiation dose, low dose-rate, low changes in dose-rate, and situations imposing a *detriment-adjusted nominal risk coefficient* of $10^{-5\,\mathrm{mSv}\,-1}$. The equation $10^{-2}\,\mathrm{Sv}^{-1} = 10^{-5\,\mathrm{mSv}\,-1}$ is at the core of a conceptual problem that this paper aims to underline: whereas this equation is mathematically coherent, it can be strongly argued that it is epistemologically incoherent. The left represents a proven fact; namely, a truth demonstrated by evidence, while the right represents an inferred conjecture; namely, an opinion or conclusion based on incomplete information.

Nevertheless, on the ICRP basis outlined above, a theoretical dose-response relationship has been synthesized by the United Nations Environmental Programme (UNEP 2016) as in the graph shown in Fig. 1.

The doses are expressed as:

- “High doses” (a few thousands of mSv);
- “Moderate doses” (a few hundreds of mSv);
- “Low doses” (a few tens of mSv); and
- “Very low doses” (a few mSv).
- It should be noted that the global average natural background dose is 2.4 mSv y^{-1} (UNSCEAR 2008c). Typical high background values could be around 10 mSv y^{-1}, and very high natural background values have been found in a few areas of the world where they are even well above 100 mSv y^{-1} (UNSCEAR 2008c).
- The probabilities are expressed in percentages between 0% and 100%, where:
- 100% corresponds to the certainty that the effect will occur; and
- 0% corresponds to the certainty that the effect will not occur.

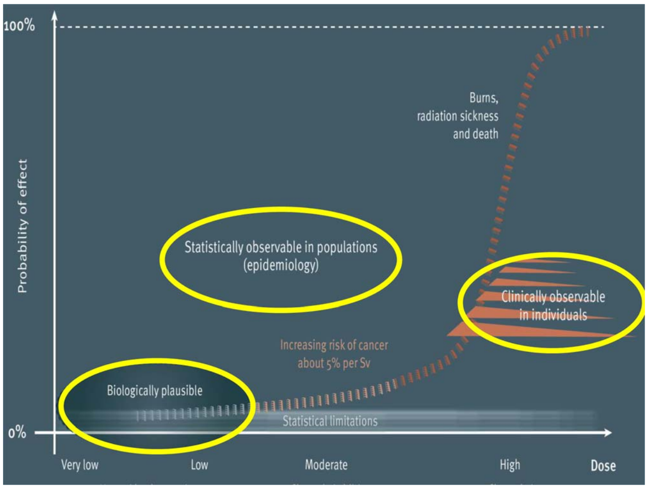

Fig. 1. A theoretical dose-response relationship.

It has to be noted that the probabilities are of two distinguishable types:

- Frequentist probabilities, which are in the high-dose area, are based on evidence; namely, on the truthful and verifiable existence of an increase in the frequency of radiation health effects in a cohort of exposed people and are defined as the limit of the relative frequency of incidence of the effect in a series of certifiable epidemiological studies on such cohorts; and
- Subjective probabilities (sometimes also confusedly termed “Bayesian”), which are conjectured for the low-dose area, expressed as a possible expectation that radiation health effects might occur, and are quantified by a personal belief or expert’s judgement; that is, not necessarily substantiated by the frequency or propensity that the effects actually occur at such levels of dose.

Both frequentist and subjective probabilities are mathematically compatible but epistemologically very different: the first is based on factual evidence, and the second is based on subjective conjectures (i.e., extrapolations that lack experimental evidence).

We further note the importance of distinguishing between the following factors:

- Verified observations of health effects in exposed individuals and populations, which allow their occurrence to be attested by qualified professionals and, therefore, such effects to be unambiguously attributed to the exposure situations that generated them; and
- Theoretical projections of health effects (marked as biologically plausible in Fig. 1), for which occurrence is feasible but not verifiable; namely, those projections allowing only some conjectural inference of risks.

As indicated before, given the current state of knowledge, radiation health effects in individuals exposed to radiation can only be attributed with confidence if they were diagnosed and their occurrence attested by a radiopathological specialist. These deterministic effects are usually acute and occur early in individuals exposed to high doses of radiation. They do not occur unless the dose exceeds a certain high threshold value.

In the low- and medium-dose regions, there is currently no factual way to attribute radiation health effects to a specific individual who is part of an exposed cohort because, for the time being, there are no biomarkers that allow that determination. Notwithstanding, collective increases in the background incidence of health effects associated with radiation exposure can be determined as a result of epidemiological studies. But, as emphasized before, statistical and epistemic uncertainties make any factual determination of such damage unfeasible when the doses are low. It is only through radiation biology that some mechanistic insight is possible. Research over the past couple decades within the radiobiology community has provided new insights regarding the existence of health effects at low doses, including claims on detrimental, beneficial, or no effects. Additional research is likely necessary before such findings can achieve the reproducibility and reliability required to include the complexities necessary in developing a universally accepted radiobiological model for evaluating the ultimate health effects of low-dose radiation exposure.

This situation has resulted in a dilemma for regulators during the implementation stage. The random nature of stochastic effects, along with the paradigm recommended by ICRP and established in international and intergovernmental safety standards, make it impossible to derive a clear distinction between “safe” and “dangerous.” This has created difficulties in explaining the control of radiation exposures, however small they may be, and has likely been a significant cause of the public fear of radiation. The major implication of the ICRP paradigm and of the consequent international and intergovernmental safety standards is that some risk is assumed—notwithstanding the clear evidence that factual health effects from low radiation dose levels have been conjectured but not proven in people.

DOSE RATE AND DOSE-RATE CHANGE

The radiation protection paradigm and its derived safety standards are based on the quantity dose, incurred or committed over a period of time, usually 1 y. However, one area that has received little focus to date is the influence of both the dose rate and the rate of change of the dose rate (namely, of the first and second time-derivatives of dose) on the ultimate health effects of radiation exposure, and, therefore, on the protection paradigm and its derived standards. The dose rate seems to be certainly relevant, and the rate of change of dose rate may be relevant as well, but the information available on the latter is minimal, although some experimental evidence on its influence exists (Brehwens et al. 2010).

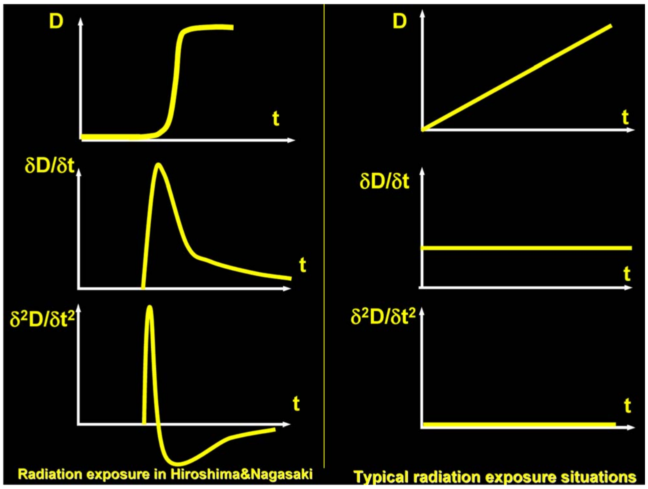

Fig. 2. On the left the figure presents the idealized time variation of dose (D), dose rate (δD/δt) and change of dose rate ($\delta^2D/\delta t^2$) caused by the explosions in Hiroshima and Nagasaki; on the right the same variables are presented for a typical radiation exposure situation.

Much of our data base for high radiation dose comes from the atomic explosions in Japan, and it is abundantly clear that not only the dose but also the dose rate and the rate of change of the dose rate for those situations was enormous. However, in most radiation exposure situations, the dose, the dose rate, and the dose-rate variation are low, and thus the rate of change of dose rate is basically zero. Fig. 2 illustrates these important differences.

One of the few exposure situations that features changes in the dose rate is the exposure of aircrew and passengers to cosmic rays during some minutes following departure and before landing, where both the dose rate and the rate of change of dose rate vary. But the change is protracted over time and, furthermore, the available epidemiological data for these cohorts is minimal for estimating health effects.

Hence, we remain open to learning more about how this may have factored into our understanding of the actual health effects of ionizing radiation at low doses.

ATTRIBUTION VS. INFERENCE

From the discussion above, it can be concluded that there are currently two domains in the dose-effects relationship, namely:

- A domain above a certain dose range, in the moderate and high dose area, where either pathological diagnosis or epidemiological evidence can be gathered in order to attribute to radiation either deterministic effects in individuals or stochastic effects in cohorts of exposed people; and
- A domain below this range where there is biological information suggesting that radiation health effects might be plausible and that a risk could be subjectively inferred, e.g., for regulatory purposes. In this low and very low domain, the risks in the current regulatory framework are generally inferred by the expert judgment of radio-protectionists.

Unfortunately, the attribution of factual effects of low-level radiation exposure (usually termed epistemology) is far too often based on conjectured estimates; namely, opinions or conclusions inferred from incomplete information. This is a serious problem. Understanding that such risk is conjectural is crucial for the debate on the perception of low radiation

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[4] Gonzalez AJ. Attributions of health effects to radiation vis-à-vis inference of radiation risk: ICRP recommendations and UNSCEAR reporting. In: International Joint Conference Radio 2017. V Congresso Brasileiro de Proteção Radiológica, VI Congresso de Proteção Contra Radiações de Países de Língua Portuguesa e VII Congresso Internacional de Radioproteção Industrial. Organizado pela Sociedade Brasileira de Proteção Radiológica em cooperação com a Agência Internacional de Energia Atômica, Sociedade Portuguesa de Proteção contra Radiação e ABENDI, Cidade de Goiânia, 25–29 September 2017.

doses because this has not been explained to members of the public and their representatives in positions of authority. The epistemological limits around the radiation sciences, which are essential for clarifying the radiation protection paradigm, have been amply debated in the literature (Gonzalez 2011b, 2014a and b Wieland and Gonzalez 2018)[4] and recently have been addressed by the IAEA (IAEA 2022a).

STUDYING RADIATION EFFECTS

There are four primary professional specialties focused on studying radiation health effects:

- **Radiation-pathologists**. Experts who are able to diagnose, attest and attribute to particular exposure situations the end result of radiation-induced diseases <u>in exposed individuals</u>. These experts diagnose on the basis of their professional experience and also using laboratory samples of body tissue for diagnostic or forensic purposes. Their field of competence and possibility of diagnosis, attestation, and attribution are limited to deterministic effects, and therefore only to high doses;
- **Radiation-epidemiologists.** Experts who use medical statistics (specifically the statistics of epidemics) to estimate the prevalence of health effects, such as stochastic malignancies, that could be associated to radiation in <u>exposed cohorts of people</u> (not in individuals). Since these effects usually have a relatively high background incidence, epidemiologists aim at quantifying increases in such incidence in a cohort following their radiation exposure. Both epistemic and statistical limitations restrict the possibilities of epidemiological estimates of stochastic radiation effects to medium and high doses incurred by cohorts of people. However, epidemiologists' competence for estimation and attestation should in principle be restricted to situations where there is an epidemic in the cohort, namely where changes in the incidence of effects can be observed and measured (as it was the case in the Hiroshima and Nagasaki cohort). Alas, many radiation epidemiologists have extended their estimates to the low-dose region by conjecturing that the same epidemics that they can observe and quantify at high doses also occur at low doses–despite that such an epidemic cannot be seen but only conjectured;
- **Radiation-biologists**. Experts who focus on the mechanistic biological changes attributed to radiation exposure (e.g., evaluating the progression of molecular changes caused by radiation up through cells, tissue, and organs). They can provide scientific insight to the mechanisms of induction of radiation health effects, and they are also able to attest the occurrence of radiation exposure in individuals by using biological indicators. However, they cannot yet reliably attest to the occurrence of ultimate health effects in either exposed individuals or in cohorts; and
- **Radiation-protectionists**. Experts associated with conjecturing and inferring radiation risks on the basis of the information provided by radiation-pathologists, epidemiologists, and biologists, in order to provide guidance for the protection of people and the environment against exposure to radiation.

After including a summary of what is meant by the term "risk," this article will then focus on some of the key issues related to the above disciplines. It is noted that it is uncommon that specialists in these four very different disciplines directly interact with an open ear to understand the full complexity of the effects of low-level radiation. As a result, the lack of convergence in their work has led to some confusion and, understandably, has likely become another element leading to the current unnecessary public fear of low-level radiation. Among several attempts to bring these disciplines together, the American Nuclear Society joined with the Health Physics Society in sponsoring a conference in 2018 (Health Physics 2020) to bring together key international specialists in these four (plus related) disciplines. A summary of the conference outcome is referenced (Feinendegen 2020).

RADIATION RISK

The word "risk" can mean many different things to many different people, including professionals. Following is a short overview of this concept in relation to radiation, which has been amply discussed at the international level (Gonzalez 2019).

For the professional community, <u>risk</u> is formally defined in international safety standards (IAEA 2007) as, alternately:

- The probability of a specified health effect occurring in a person or group as a result of exposure to radiation;
- The mathematical mean (expectation value) of an appropriate measure of a specified (usually unwelcome) consequence; and
- A multi-attribute quantity expressing hazard, danger, or chance of harmful or injurious consequences associated with actual or potential exposures.

These are very different concepts, and the use by professionals of all of them has certainly not helped to facilitate the understanding of risk at low doses.

But for the non-professionals, the meaning of risk can be very different than the different concepts used by professionals. The general public often associate risk with a variety of connotations including chance, plausibility, likelihood, prospect, hazard, imperiling, jeopardizing, gambling, betting, wagering, venturing, danger, peril, threat, menace, fear, and endangering. Threat, menace, and fear have been the main public connotations of radiation risk and have fueled the public fear of radiation.

Historically, the quantification of "risk" was formed on a retrospective analysis of actual experience on factual frequencies of past occurrences and was thus quantified with a "frequentist" probability; namely, a probability calculated from the frequencies of factual occurrence of the risky event. However, over time, the concept of "risk" evolved, particularly for radiation protection, and is now often also referred to as a subjective probability of occurrence resulting from experts' judgments, which are sometimes based on estimates of frequentist probabilities but from different situations. Thus, due in large part to the lack of factual data of health effects at low doses, conjectures are made extrapolating risk estimates from high-dose radiation exposure situations to low-dose situations.

The concept of frequentist probability was and continues to be the basis for epidemiological estimates and should provide the core scientific basis for radiation protection at doses above the levels at which stochastic effects are seen. Originally, radioepidemiological estimates were generally performed using data on frequencies of such actual health effects factually incurred in the aftermath of past radiation exposure situations. Such events usually involved relatively high doses and high and highly changing dose rates, such as those affecting the cohort of Hiroshima and Nagasaki survivors. Alas, this frequentist radioepidemiological practice was extended to low-dose radiation exposure situations for which a prevalence of radiation-induced disease is not identifiable; namely, where there are not frequencies providing a basis for the assignment of frequentist probabilities. These situations would epistemologically be considered to be outside the domain of radioepidemiology. However, extrapolations from the frequentist experience have been used for providing estimates and, with the help of experts' subjective judgments, notional radiation risks have been inferred as a subjective probability quantifying a potential increment over the background prevalence of effects.

On these bases, both frequentist and subjective radiation risks are expressed in radioepidemiology indistinctly as excess absolute risk, meaning the rate of disease in an exposed population minus the rate of disease in an unexposed population. They are also expressed as excess relative risk, i.e., the rate of disease in an exposed population divided by the rate of disease in an unexposed population minus one. In addition to these two main denotations, a large number of risk-related terminologies are somehow confusedly used in radioepidemiology, a notation that may be contributing to public fear.

The puzzlement caused by the different denotations and connotations of the word "risk" have permeated the field of radiation protection. In the descriptions of the radiation protection paradigm and in the radiation safety standards, the word risk is used prolifically and in dissimilar ways, without specifically describing the meaning of the term each time it is used. Notably, a detriment-adjusted risk is defined as the probability of the occurrence of a stochastic health effect, modified to allow for the different components of such detriment in order to express the severity of the consequence(s). The detriment is a multidimensional concept including stochastic and conjectural components, such as probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and length of life lost if the harm occurs.

Thus, the radiation protection paradigm is based on a radiation weighted risk-dose model estimated by extrapolation of high-dose data, without a dose threshold.

In its publication 60, ICRP had engaged in a sophisticated analysis of the concept of risk but avoiding the crucial distinction between frequentist and subjective probabilities. That recommendation included the formulation of precise, but again conjectural, quantities defining risk, including the total probability of death (used as a reference) and the conditional and unconditional death probability rates. These quantities would eventually evolve into several types of estimates that can be used to calculate conjectural lifetime risk; namely, the subjective probability that individuals will develop, or die from, a specific disease caused by radiation exposure. These estimates include:

- The excess lifetime risk, which is the difference between the proportion of people who develop or die from the disease in an exposed population and the corresponding proportion in a similar population without the exposure;
- The risk of exposure-induced death, which is defined as the increment in a cause-specific death rate accumulated over a lifetime, as an additional cause of death introduced by radiation exposure;
- The risk of losing life expectancy, which describes the decrease in life expectancy due to the exposure of interest; and
- The lifetime attributable risk, which is an approximation of the risk of exposure-induced death and describes excess deaths (or disease cases) over a follow-up period with population background rates determined by the experience of unexposed individuals. The lifetime attributable risk is used by ICRP to estimate lifetime risks and for establishing dose restrictions, but unfortunately it was not clearly indicated that lifetime attributable risk is a conjecture (i.e., based on opinions or conclusions inferred from incomplete information).

It is to be emphasized that the distinctiveness of the frequentist vis-à-vis subjective interpretation of risk is not specifically recognized in the ICRP paradigm. The frequentist probabilities arising from the epidemiological studies of populations exposed to relatively high doses and high dose rates are used to figure subjective radiation risk estimates for low-dose low-dose-rate exposure situations, and no specific distinctions are made between these two probabilities.

It is clear there are many nuances that come into play when discussing risks, and radiation risks in particular. A comprehensive discussion of such nuances is addressed in the literature (Gonzalez 2015). For the purpose of this paper, it should be simply recognized that all four fields of the relevant sciences, i.e., radiation epidemiology, radiation biology, radiation pathology, and radiation protection, play an important role in understanding the actual health effects of radiation. Whereas disagreement often exists within these fields regarding the interpretation of the health effects resulting from radiation exposure, there is ample and convincing evidence that there is no legitimate reason for the public to remain fearful of exposure to low radiation levels.

In summary,

- A provable radiation risk for individuals occurs only for exposure to high-dose radiation (the deterministic domain and the medium and high dose-epidemiological domain). People ought to fear risk due to the effects resulting from high and medium doses, but such effects are not attributable following exposure to low radiation doses.

LEGAL CONSIDERATIONS

The ability to attribute health effects to specific radiation exposure situations can influence the legal capability to impute damages from those suffering detrimental effects to those responsible for the exposure. The imputation may include assigning liabilities for physical injuries or harmful effects inflicted on those who received the exposure.

For deterministic effects, the legal process is straightforward, and the radiopathologist diagnosing the effect is a proper and sufficient expert witness who can legally attest in court to the factual occurrence of the effects. But for stochastic effects, individual attribution is not feasible. In some legal jurisdictions (Gonzalez 2022), collective imputation (sometimes termed as "class action") is feasible, and radioepidemiologists would be appropriate expert witnesses. However, such class actions are not obtainable in all jurisdictions (Gonzalez 2022).

For situations where the radiation exposure is in the low or very low region, there is no factual basis to impute damage since the inferences of risk are based only on subjective (conjectural) expert judgment. Far too often, this caveat is missed in legal proceedings, and awards for workers or members of the public subjected to these low-dose exposures are based on emotions or political convenience rather than science. These situations are often publicized and have also likely contributed to the public fear of radiation.

In some jurisdictions where legislation is not codified and for occupational cases, it has been agreed to use factual exposure data to determine a conjectural "assigned share" of the radiation damages. This "assigned share" is determined by first evaluating the hypothetical relative risk of the situation. The excess risk is then the risk incurred beyond the relative risk, and the assigned share is simply determined as the excess relative risk divided by the relative risk.

The overall issue of attributing workers' harm to occupational exposure was addressed by the International Labor Organization without a clear output (ILO 2010). The wider issue of imputing harm to radiation exposure situations had been discussed in the international legal literature (Gonzalez 2002, 2014c) and has been one of the topics of a recent IAEA book on nuclear law (IAEA 2022b).

A definitive clarification of the imputability of harm to radiation exposure might be crucial for limiting the public fear of low radiation doses.

THE LINEAR NO-THRESHOLD REGULATORY APPROACH

During the early years following the discovery of radiation, this new phenomenon was generally revered as an exciting new methodology for diagnosing broken limbs during World War I and even as a "tonic" for improving health. But like many other new discoveries, it was sometimes used in excess—causing skin burns and other health impairments—and this prompted new experiments to determine safe dose levels.

Perhaps the most influential work was done by Herman Muller (Calabrese 2019) when he irradiated fruit flies and concluded that the relationship between dose and damage was linear, with no threshold. Even though his data were obtained at very high dose rates (thousands of times higher than low-level radiation), he was later awarded a Nobel Prize for related mutational studies, providing a high measure of notoriety, with a follow-up endorsement of his linear model by the National Academy of Sciences (NAS) in the mid-1950s (Calabrese and Giordano 2022).

Although there may have been other factors in addition to Muller's early work that came into play, his work led directly to the acceptance of the linear no-threshold (LNT) model. Thus, in spite of the many caveats in the ICRP recommendations, LNT has been adopted in international safety standards and almost universally used within the international radiation protection community as a practical tool for regulating radiation exposure.

But a major controversy is building within the radiation protection community. Some research (Calabrese et al. 2022), along with an extensive video series pioneered by the Heath Physics Society (Cardarelli et al. 2023), provide considerable support for how professional deception may have crept into the adoption of the Muller's original LNT premise.

Given the questionable ethics revealed in the Calabrese investigations (Cardarelli 2023), it is not surprising that the meaning of the LNT model is multiple and imprecise. It is intended to mean "a linear dose-response relationship with no threshold of dose," but there is ambiguity in its precise understanding, with interpretations including the following:

- For some it is a premise; namely, an underlying assumption that radiation carries a risk at any level;
- For others it is a hypothesis; namely, a supposition or proposed explanation of the relation between health effects and incurred radiation dose, which is made on the basis of limited evidence as a starting point for further investigation; and
- For others it is a model; namely, a simplified description of a complicated phenomenon that is useful only for practical operational purposes.

These various views of the LNT have permeated the different professional communities involved in the issue. Given this controversy, LNT has been used with different denotations by the relevant professional communities and with many connotations absent specialized audiences, thus likely becoming a significant cause of confusion contributing to the public fear of radiation.

LNT has been viewed by the various radiation professional communities with the following simplified descriptions.

Radiopathologists

For radiopathologists, LNT is neither apparent nor needed, neither as a premise nor as a hypothesis nor as a model. Radiopathologists look for factually diagnosed effects on individuals who have been exposed to high radiation doses. The dose-response relationship is a sigmoid curve presenting a de facto dose threshold.

Below the dose threshold, radiation effects are, for a radiopathologist, neither diagnosable nor attributable in individuals. It should be noted, however, that radiopathologists may use specialized bioassay specimens (such as some hematological and cytogenetic samples) as biological indicators of radiation exposure, even at doses below the threshold. Nonetheless, UNSCEAR has indicated that 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 (UNSCEAR 2012b).

Radioepidemiologists

For radioepidemiologists, LNT is a hypothesis, an epidemiological conjecture by which changes in the background incidence of deleterious effects associated with radiation, such as malignancies, per unit dose, can be measured. Indeed, radiation exposure situations involving relatively high doses, delivered at relatively high dose rates and involving substantive time changes of the dose rate, have been made. But all too often, radioepidemiologists have presumed such changes occur equally at radiation exposure situations involving low doses and low dose rates with no change in the dose rate—in spite of the fact that epidemiological evidence is not achievable in such situations due to epistemic and statistical limitations.

Stated differently, for radiation-epidemiology, LNT means that the incidence of effects per unit dose at high doses, high dose rates, and high dose-rate changes, which is backed up with epidemiological evidence, remains the same at low doses and low dose rates with no significant changes in the dose rate, in spite of the absence of epidemiological evidence.

Epidemiology is a very serviceable science where an epidemic exists, such as the epidemic of radiation effects that followed the bombing of Hiroshima and Nagasaki or the epidemic of pediatric thyroid cancer that followed the high thyroid doses incurred by children that ingested highly contaminated milk following the Chernobyl accident (UNSCEAR 2008c). But such an epidemic has not been visible for low-level radiation exposure situations. It is only presumed to exist. The existence of effects is just conjectured because—should they exist—they cannot be seen due to the epistemic and statistical limitations of epidemiological sciences. It is simply unfeasible (namely, impossible and impractical to achieve easily or conveniently) to accrue sufficient statistical data for low-dose exposure situations in order to observe actual health effects due to those epistemological constraints.

UNSCEAR has been evaluating epidemiological studies of cancer and cardiovascular diseases for years (UNSCEAR 2006a). In recent years, UNSCEAR conducted a reevaluation for inferring cancer risk to exposure at low dose rates from environmental sources (UNSCEAR 2017a). The overall results of those studies imply that the risk of cancer per unit dose is smaller for low-dose than for high-dose situations—although uncertainty still exists due to the low statistical power associated with low-dose radiation. Environmental radiation exposure typically results in low and moderate doses, and therefore, potential excess cancer risks may be expected to be small or nonexistent.

The estimation of such small and inferred incremental risks of cancer from protracted radiation exposures could easily be affected by confounding due to other cancer risk factors. It is important to emphasize that radiation is just one of the risk factors for cancer. It is unlikely that radiation acts independently from other risk factors in cancer development (such as smoking, diet, etc.). This may contribute to the differences between study results because the existence of confounders and their association with radiation exposure can vary. An analysis accounting for the effects of confounders also sets requirements for sample size in a study. But even within this context, meta-analysis or pooled analysis of piecemeal data has limitations no matter how large the sample size. Demonstrating the insignificance of low-dose exposure compared to other lifestyle factors in well-organized epidemiological studies (e.g., Kudo et al. 2022) will be more meaningful as real-life evidence. Precise estimates of health effects and their frequencies need sufficient follow-up, case ascertainment through high-quality cancer registry systems, and accurate information on risk factors other than radiation exposure. This emphasizes the need for prospective long-term studies with high-quality dosimetry, as well as comprehensive and accurate outcome data and information on cancer risk factors other than radiation exposure.

The quality of radioepidemiological studies is a key issue. The current preferred methods of evidence synthesis are systematic reviews, meta-analyses, and pooled analyses, which are regarded as the state-of-the-art scientific standards for pooling research data and are deemed superior to traditional narrative reviews. There are principles and criteria for ensuring the quality of the reviews of epidemiological studies that take into account these scientific developments. It should be noted that the specific nature and scientific contents of such studies do not allow for a mechanistic application of generic quality assurance criteria and, therefore, UNSCEAR has developed an approach to assess the quality of such studies and to synthesize the findings from many studies into its inference of radiation risks. This is published as a report on principles and criteria for ensuring the quality of the UNSCEAR's reviews of epidemiological studies of radiation exposure (UNSCEAR 2017b).

UNSCEAR has discussed the relevance of the dose and the dose-rate effectiveness factor (DDRF), a radiation protection concept, in the context of scientific evaluations of epidemiological studies of cancer risk from low dose-rate exposure. It concluded that the dose-response relationships depend on a large number of factors such that the scientific evidence regarding a possible reduction in the radiation-induced effects per unit dose at low doses and low dose rates relative to acute exposures with moderate or high doses cannot be expressed by a single value. Due to this plethora of factors, the appropriateness and need of the DDRF concept have been deeply questioned (Gonzalez 2017).

UNSCEAR continues to review the developments in epidemiological, biological and statistical analyses that contribute to improved inference of risk, if any, following low-dose and low dose-rate environmental exposures. Meanwhile, UNSCEAR encourages applying radiobiological data derived over the past couple decades to help understand the lack of observable cancer incidents following the exposure to low doses, even without knowing with certainty the precise mechanisms involved.

In summation, the radioepidemiological meaning of LNT should reflect the fact that the epidemiological outcomes from low-dose radiation exposure situations are only conjectural inferences; namely, the effects are not attestable and cannot be attributed. Looking to the future, UNSCEAR recommends combining a mechanistic understanding of low-dose radiation carcinogenesis with epidemiological studies using mathematical modeling integrating data from experimental systems (e.g., dose-response data for induction of key mutations or epimutations).

Radiation-protectionists

For radiation-protectionists, LNT represents a <u>model</u>, i. e., a simplified description of reality, which is practical and workable for managing operational radiation protection, particularly in occupational radiation protection, by exercising protection against additional doses regardless of the level of accumulated dose.

If this model is not used for the protection of workers, it may necessitate assigning different protection for the same increase in doses, depending on the accumulated dose. This could unavoidably create discrimination among workers, such as age-related considerations, which is prevented by the current international labor legislation.

Radiobiologists

For radiobiologists, LNT was originally taken as a <u>premise</u> postulating that at low radiation dose exposures, a given increment in dose would produce a directly proportionate increment in the probability of incurring cellular effects that would evolve into malignancies or heritable effects attributable to the radiation exposure.

The early radiobiological assumption was that the main interactions of radiation with living matter were “targeted” direct and indirect interacting effects with the cellular DNA causing mutations that could evolve into associated detrimental effects such as malignancies. However, biological research over the past few decades has increased the understanding of how radiation interacts with the non-linear complexities of living tissue. Accordingly, it is important to delve a bit deeper into the biological aspects of radiation exposure at low levels, since the development of a scientifically-based premise to review and eventually revise the LNT premise can only be accomplished and accepted by the broad radiation health professional community when the detailed biological processes are understood (Brooks et al. 2023).

Detailed radiation biology research over the past few decades has revealed many secondary, “non-targeted,” effects, including the following (UNSCEAR 2006b):

- Radiation-induced genomic instability, in which if a single cell is irradiated and survives, it may produce daughter cells that over generations have increasing numbers of mutations;
- Adaptive response, which expresses the proven ability of cells and tissues in all organisms to respond to a number of different challenges to better resist stress damage, e.g., also caused by radiation exposure (in this context, adaptive protection appears to operate by prevention of DNA damage, repair of damage, and by damage removal);
- Bystander effects, namely the ability of irradiated cells to convey manifestations of damage to neighboring cells not directly irradiated;
- Abscopal effects, which are said to occur if there is a significant response in a tissue that is physically separate from the region of the body exposed to radiation; and

- Induced clastogenic factors, which result from a large body of evidence that blood plasma from irradiated animals and humans can contain so-called "clastogenic factors" capable of inducing chromosomal damage in unexposed cells.

In the early phases of research, there was a concern for heritable effects, i.e., effects that might be observed in offspring born after one or both parents have been irradiated prior to conception, and UNSCEAR studied the issue in depth (UNSCEAR 2001). However, such heritable effects have not been seen in humans, and UNSCEAR has concluded that "although demonstrated in animal studies, an increase in the incidence of hereditary effects in human populations cannot at present be attributed to radiation exposure" (UNSCEAR 2012b).

Some of the manifestations of these non-targeted and delayed effects can in principle arise spontaneously and after exposure to other agents. These effects have led to different assumptions, ranging from (1) the possibility that low radiation doses produce beneficial effects (hormesis) rather than damage, to (2) the possibility that low-dose exposure brings higher risks than hypothesized from epidemiological studies.

The causes of the various types of responses to irradiation depend on the interaction of energy deposition events with sensitive structures at the various levels of biological organization (ICRP 2015; UNSCEAR 2021). Thus, exposure to fields of ionizing radiation creates energy depositions along tracks of subatomic particles of microscopic dimensions. Such energy deposition events are distributed by chance in exposed matter such as biological tissues. At the molecular level, the energy depositions occur stochastically. For example, in a radiation field of 100 kV x rays, an average energy deposition event per nanogram tissue (an average cell mass) constitutes around the equivalent of 1 mSv. Thus, the typical limiting levels of radiation doses being regulatory controlled for members of the public, namely 1 mSv per year, would lead to one energy deposition event per nanogram per year; namely, around one interaction per cell per year.

The major concerns of such exposure are any especially serious damaging changes of the genetic material, the DNA, with immediate attempts of repair, and subsequent alterations of cellular signaling control mechanisms.

In general, biological responses to low doses of ionizing radiation are twofold: primary events following energy deposition, and secondary responses to the primary events. These latter responses appear within hours after exposure and may last over long times. Since the types and degrees of secondary responses are under genetic control, various degrees of radiosensitivity exist among the human population.

The issue of radiosensitivity is complex. The effects of radiation up through the chain of cell structure to complex organs can vary among individuals, including the age and gender of each individual. However, the ICRP has addressed such effects (ICRP 1998), principally the genetic vulnerabilities for cancer, and has concluded that such variables have been well accounted for in their overall guidance. Whereas variations in radiosensitivity could be of importance if radiation doses are high, it is highly unlikely that they can be of significant concern for low-dose radiation. Any effects of low-dose radiation, if any, are almost certainly overwhelmed by other factors.

Regarding the major effects from low-dose and low dose-rate radiation, the following reporting (Feinendegen and Cuttler 2018) summarizes key outputs from considerable biological research:

- Low doses of ionizing radiation to exposed cells, quite different from high doses, cause in experimental biological systems potential protective cellular signaling changes that are fairly large in comparison with relatively very few potentially serious DNA damages, and most such damage is basically repaired relatively rapidly. As dose rates increase, the number of "hits" increase in a linear fashion. But the signaling changes that follow are manifest in a non-linear fashion in complex biological systems. In particular, adaptive response-protections with beneficial consequences have been measured to reduce spontaneous damage in the exposed system. Other secondary responses (referred to earlier) include genomic instability, bystander effects, and abscopal effects that have been observed at higher doses (Brooks et al. 2016);
- At chronic low dose-rate exposure, repair mechanisms and secondary responses reduce or prevent cellular damage accumulation. Any cell damage that does occur needs to become propagated through the increasingly complex levels of biological organization in order to cause late detrimental health effects. Such damage, if any, and the propagation of such damage, is an inherently non-linear process (Feinendegen et al. 2010);
- Secondary responses to low doses of radiation have been unequivocally observed in the human body. Yet, the significance for them to cause clinical health effects is still being debated. Whereas some conjecture remains, it has been argued that essentially all biological systems contribute positive health results at low doses (e.g., medications, vaccinations, trace elements, etc.) but result in considerable damage at high doses; simply put, the poison is in the dose;
- Radiation biology data indicate that the probability of a clinical malignancy in the human body following low-dose exposure, if it occurs at all, is small. Spontaneous damage from physiological reactive oxygen species (ROS), the key reaction providing essential energy for life itself, is far more frequent. Yet our bodily protective system (immune system) clearly accommodates and effectively repairs such damage. Further discussion of this powerful immune system is included below;
- Contrary to earlier concerns that cellular damage can occur even at low levels of radiation, recent experimental

evidence has revealed just the opposite; namely, that biological systems apparently require a certain low level of radiation to survive and thrive (Waltar and Feinendegen 2020); and

- In general, living systems protect themselves against damage by preventing damage to arise, repairing damage that occurs, and removing damage that escapes repair. The removal is a key component of the immune system.

An issue that has been widely discussed by the radiobiology community is the effect of ionizing radiation on the immune system. The issue has been deeply reviewed by UNSCEAR since 1972 (UNSCEAR 1972). The immune system is one of the most complex systems of the human body. It relies on highly specialized cells with their specific function of providing a very complex set of biochemical reactions that yield several types (lymphocytes and accessory cells) strategically spread throughout the body, perfectly positioned to recognize antigens (non-self or foreign substances and cells) and to neutralize or destroy them. This system protects against infections and cancer. There are two different but interrelated forms of immunity: innate and acquired immunity. Innate immunity is fully functional before any foreign agent enters the body and thereby provides a rapid defense. Acquired immunity develops after a pathogen has entered the body and maintains memory of previous exposures, yielding a stronger response following subsequent exposure to the same antigen. Acquired immune responses are mainly executed by B-lymphocytes (humoral responses) and T-lymphocytes (cell-mediated responses) (Feinendegen et al. 2011).

The effects of ionizing radiation on the immune system can be assessed by estimating changes in cell numbers or by using a variety of functional assays. The impact of such alterations in immune response depends on factors such as the dose of radiation, its temporal relation to immunization, and genetic disposition. There is no doubt that high doses of radiation produce immunosuppression, mainly due to the destruction of cells. Lymphocytes are very radiosensitive, and their reduction is currently used as an early indicator of the level of an accidental acute exposure. Radiation-induced changes in immune parameters seem to be more dependent on total dose than on dose rate (Liu et al. 2020). Persisting effects on the immune system have been observed after exposure to high doses.

At low doses and low-dose rates, low dose-rate changes, and the effects of ionizing radiation on the immune system might be suppressive or stimulatory or none. Some experimental data appears to reveal that using low-level radiation to stimulate the immune system would limit flu symptoms (Calabrese and Dhawan 2013), but the long-term impacts of these low radiation doses on the immune functions in relation to human health have not been evaluated. Many people throughout the world routinely visit radiation health spas (e.g., mines where the radiation level is well above natural background) and claim considerable relief from nagging health issues.

UNSCEAR has concluded that while the suppressive effects of high doses of ionizing radiation are well documented (UN 2014), uncertainty exists regarding the effects of low radiation doses on the immune system since both stimulatory and suppressive effects have been reported.

In spite of this new information, there continues to be considerable debate regarding the causal relationship between the non-targeted effects and the observed health effects attributable to radiation. UNSCEAR concluded several years ago (UNSCEAR 2006c) that the estimation of the health effects of radiation should be based on epidemiological observations where there is a statistically significant dose-related increase in disease incidence. These direct observations of adverse health outcomes would implicitly take account of mechanistic elements relating not only to the targeted (direct) effects of irradiation but also to the non-targeted and delayed effects.

Recent UNSCEAR estimates (UNSCEAR 2019) on the biological mechanisms relevant for the inference of cancer risks from low-dose, low dose-rate radiation acknowledges the existence of secondary responses following low-dose radiation exposure as described above. But because of the uncertainties of these secondary responses, which are small and difficult to detect accurately for low-dose situations, UNSCEAR remains cautious regarding their consistency, disposition, and reproducibility.

Given these uncertainties, UNSCEAR judges there is still insufficient justification to recommend changes in the current radiobiological paradigm on the basis of these secondary responses. Here, UNSCEAR claims that so far, there is a considerable degree of uncertainty regarding the mechanisms bridging secondary responses to clinical cancer. In this context, it should be emphasized again that the incidence of cancer at very low doses cannot be measured for epistemological reasons unless large populations (enough to be statistically significant) are being studied. Further, given the heterogeneity of individuals for various aspects, the risk of cancer at very low doses could not be evidenced even if a large number of individuals were studied.

In summarizing the recent research within the radiation biology community, despite remaining uncertainties as to whether and to what degree adaptive protection always operates against radiogenic and non-radiogenic damage, any radiation health effects at low dose, if they exist at all, are almost always dwarfed by other toxins that we live with every day, such as the natural bodily burning of oxygen so essential to life.

MISUSE OF LNT AND RADIATION FEAR

The wide and imprecise use of the acronym LNT, without clarification of its real meaning, has likely been a cause of serious confusion about the health effects attributable to radiation exposure situations involving low dose, low dose rate, and low dose-rate change. This is most disturbing because these are some radiation exposure situations associated with the many beneficial uses of radiation.

The wider but epistemologically wrong connotation of LNT has been the improper use of the quantity termed collective dose. The collective dose is an extensive quantity (differently from the intensive quantity dose), which is defined as the total radiation dose incurred by a population. An improper use of this quantity has been to integrate the low dose of an individual cohort member and multiply it by the total number of people in that cohort—resulting in a large hypothesized number of casualties. Both UNSCEAR and ICRP have warned that this approach is improper. This misuse of collective dose has been done even at academic levels, e.g., wrongly attributing to the Chernobyl accident around one million deaths (Yablokov et al. 2009)! This absurd calculation has been withdrawn, but the damage was done, and public fear of radiation was increased.

Given the misuse of such radiation risk calculations, UNSCEAR, following a specific request from the United Nations General Assembly, addressed the issue of attribution of health effects to different levels of radiation exposure. It reached a number of conclusions, significantly noting that increases in the incidence of health effects in populations cannot be attributed to low-dose radiation exposure situations. Only notional risks from planned situations may be prospectively inferred for purposes of radiation protection and allocation of resources.

Even the Holy See has weighed in on this issue. A report on biological implications of optimization in radiation protection from the Pontifical Academy of Sciences indicated that "There are reasons to believe that the assumptions inherent in the LNT model are likely to overestimate the real risk at the low doses of interest" (Pontifical Academy of Sciences 1983).

THE LNT MODEL AS CURRENTLY USED FOR REGULATORY PURPOSES

As noted earlier, the term LNT used by the radiation protection community simply refers to a practical model for managing operational radiation protection. This model assumes radiation exposure should be limited by certain dose levels. Below these levels, protection should follow a process of optimization of protection by selecting (among the available protection alternatives) the best protection option under the prevailing circumstances. It simply assumes that radiation risks might be conjectured and inferred at any level of dose.

However, if these conjectural inferences within the practical LNT radiation protection model are understood to be proven facts, a gap in understanding is created that is likely responsible for creating public fear. The serious epistemological limitations of the biological and epidemiological sciences for validating the LNT model must be recognized.

Despite these clear reservations, the LNT radiation protection model is recognized as rather easy to administer and serves as the generally accepted radiation protection model in most nations on the globe. However, as we sum up the evidence from the perspective of either radiation epidemiology or radiation biology, there is no valid reason to fear low-dose radiation exposures—in spite of the various interpretations of the LNT.

Many professionals in the radiation community now argue that the LNT model as used by the regulatory community should be revised and its purpose clarified—at least for radiation levels in the low-dose, low dose-rate domain. They base their arguments along the lines outlined above.

A new research and development program is currently being designed by the US National Academies of Science, Engineering, and Medicine (NASEM 2022) to seek the data needed to evolve a more scientific approach to the regulation of radiation exposure. Hopefully, sufficient data will be derived to provide a widely acceptable model to be embedded in regulation approaches worldwide. But this may take several years, and it is dependent on a sustained funding base that is often difficult to maintain for the duration needed.

So, what should we do in the meantime to help remove the unnecessary and destructive public fear of low-dose radiation?

POTENTIAL REGULATORY SOLUTION FOR THE LOW-DOSE CONUNDRUM: EXCLUSIONS AND EXEMPTIONS

The conundrum of protection against low-dose exposure, often caused by misunderstandings and misapplications derived from the LNT model, could be solved through a better formulation of the current regulatory approach without entering into controversial biological and epistemological discussions.

On the issue of the dose limits

For instance, taking into account the current dose restrictions established in international protection standards, it is already established (albeit not necessarily clear) that the annual dose of some individuals should not exceed 100 mSv under any circumstance (namely, the factual dose "limit"). The current values for protection criteria recommended by ICRP and established in international safety standards include such a factual limit for some emergency exposure situations. But the word "limit" is used rather differently when referring to planned exposure situations. It then refers to a "limit" of an increment of dose above a background dose that is higher than the stated "limit." To such a peculiar "limit," the published low value of 1 mSv y^{-1} for the public has been assigned. That is a cause of major confusion. It is quite reasonable that this leads the public to believe that receiving a dose above or near 1 mS y^{-1} is very dangerous. They become surprised (and perhaps relaxed) when they learn that they are continually exposed to background natural radiation at doses considerably higher than such a "limit."

It should be noted that the 1 mSv level was somehow arbitrarily selected as an annual dose limit. It traces back to a previous level of 5 mSv, which was reduced by a factor of five following a change in the dosimetry of the cohort of Hiroshima and Nagasaki victims. But that 5 mSv had been subjectively selected as one tenth of the occupational dose limit at the time, which was 50 mSv y^{-1}; namely, 1 order of magnitude lower than a value considered safe for an individual worker. The 50 mSv y^{-1}, in turn, had been derived from an "index of harm" developed by ICRP (ICRP 1977).

Over time the "1 mSv limit" was perceived as a purposely low extra dose restriction offered for the sake of the precautionary principle during a planned exposure situation involving members of the public. It should be noted that a planned exposure situation is a situation of exposure that arises from the planned operation of a radiation source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, associated exposures and their probabilities of occurrence can be restricted from the outset to low precautionary levels. In fact, the primary means of controlling exposure in planned exposure situations is by good design of installations, equipment, and operating procedures.

Constructing the idea that a real "limit" [i.e., a point beyond which an individual dose shall not pass (a terminal point or boundary for individual doses; namely, the real regulatory restriction on the level of dose incurred by individuals)] should be, and in fact already is, something closer to the 100 mSv y^{-1} level. This is recognized in current standards to be an acceptable safe limit because it is allowed to be incurred under some conditions, which are specified in the international standards. Adopting this interpretation would constitute a huge step in greatly ameliorating the unnecessary public fear of low-level radiation.

On the issue of optimizing protection

In addition, the standards require that protection be optimized; namely, that the best option (among the available protection options) be selected under the prevailing circumstances. Optimization in the general sense is intended to find the protection solution that provides the maximum benefit with the minimum disadvantages. Unfortunately, mainly due to historical reasons, optimization of protection is sometimes confused with minimization of individual doses. This is simply wrong.

A most unfortunate example of placing undue focus on radiation dose was the evacuation proceedings following the Fukushima accident. As noted in the next section dealing with social consequences, the death toll due to the long-term evacuation process resulted in a high number of actual fatalities, but none were due to the radiation exposure itself.

On the issue of regulatory scope

The low-dose conundrum could well be solved through a clear definition of the scope of what has to be regulated by introducing the key concepts of exclusion from regulations and exemptions from regulating. The concept of exemption from regulatory control was carefully considered many years ago (Linsley and Gonzalez 1988), and it was introduced in Europe very early (EC 1993); however, an international consensus has been elusive.

Regulation of radiation exposure has not included a clear definition of the regulatory scope. ICRP has made clear recommendations in this regard (ICRP 2007b), but they have been generally ignored by regulators. For instance, there is not a universal, homogeneous, coherent, and consistent incorporation of the crucial concept of exclusion and exemption recommended by ICRP into national regulations.

Legislative and regulatory authorities should exercise some efforts toward defining the scope of radiation protection control measures through legislation and regulations. For this purpose, they could use the well-established and universally accepted radiation protection principles of justification and optimization.

Some radiation exposure situations may be considered for exclusion by the legislation because their regulatory control is deemed to be unamenable or unjustified. New prudent legislation could then develop unambiguous exclusion criteria for defining the scope of radiation protection legislation by using the old legislative principle of *de minimis non curat lex*. If legislation with exclusion criteria were clearly established, it would allow tackling some controversial issues of specific exposure situations, such as exposure to cosmic rays at ground level and other natural occurrences.

In addition, regulators may exempt radiation low-level exposure situations from regulatory control on the basis that deregulation is the optimum protection option (*de minimis non curat prætor*). Such action would provide the general public a great service. This guidance would provide the basis for recognizing that, in many cases, exemptions provide the optimal solution. This would resolve the problems of regulating low-energy or non-penetrating radiation, some naturally occurring radioactive substances, low levels of radioactivity in consumer goods, and low-level radioactive residues.

Thus, the concepts of exclusion and exemption should become modern parallels to the ancient legal principles of *de minimis non curat lex* and *de minimis non curat prætor*, respectively, which originated in Roman law two millennia ago and since then have governed the legal problem of regulating trifles: namely, regulating what is inconsequential, unfeasible, unimportant, or irrelevant from the point of view either of the legislator or the regulator (trifle in this sense is not necessarily a synonym of trivial). The *de minimis non curat lex* principle addresses the situations that the law should (or should not) take account of, or cover. The *de minimis non curat prætor* principle addresses the situations, among those covered by the law, that can be freed by the regulator from some or all regulatory controls.

SOCIAL CONSEQUENCES OF RADIATION FEAR

Being fearful of some things is both understandable and harmless—doing no damage to the general public. Being afraid of the dark or being fearful of snakes may impact the lifestyle of an individual, but it has no impact on others. But being afraid of low-level radiation, where there is no justification for such fear, does cause damage to society. Following are just a few examples where such unfounded fear of low-level radiation has resulted in consequences quite detrimental to modern life.

The Three Mile nuclear accident

This accident, which occurred on 28 March 1979 near Harrisburg, PA, resulted in a partial core meltdown and a huge economic loss (Rosztoczy 2019). However, the radioactive substances released into the atmosphere were miniscule, and the theoretically calculated radiation doses were lower than the natural background doses incurred by an airline passenger flying from Los Angeles to New York. Yet the sensational negative publicity and fear generated by this event resulted in a large social impact on the population and, moreover, in a major halt in the licensing and construction of planned nuclear reactor expansions—especially in the United States. An exponential number of new licensing regulations and bureaucratic paperwork was generated, driving up the cost of new plants to the point of economic unacceptability.

The Chernobyl nuclear accident

This accident, which occurred on 26 April 1986 in Ukraine (then part of the former Soviet Union), was undoubtedly the worst nuclear accident to ever occur in the world. There was a worldwide reaction following the accident, mainly triggered by the fear of radiation. Many published articles, even by renowned academies, contained predictions of a human catastrophe assigning millions of victims to the accident. However, the factually observed health effects attributable to radiation exposure from the accident have been assessed to be <u>much lower</u> by the international scientific community (IAEA 1996b; Gonzalez 1996).

UNSCEAR reported the following radiation-related consequences from the Chernobyl accident (UNSCEAR 2008a):

- 134 plant staff and emergency workers, many of whom also incurred skin injuries due to beta irradiation, received high doses of radiation that resulted in acute radiation syndrome.
- The high radiation doses proved fatal for 28 of these people.
- 19 survivors have since died (following the reporting of 2008), but their deaths have been for various reasons and usually not associated with radiation exposure.
- Several hundred thousand people were involved in recovery operations, but there is no evidence of health effects that can be attributed to radiation exposure, with the exception of a substantial number of thyroid cancers attributed to drinking uncontrolled milk contaminated with ^{131}I. No prompt countermeasures were taken, which resulted in 15 fatalities (up to the year 2005) among children, who are much more susceptible to thyroid cancer than adults.
- Unsurprisingly, the International Conference on *Chernobyl: Looking Back to Go Forward* (IAEA 2005) concluded that "The majority of workers who participated in the cleanup efforts, the many thousands of persons evacuated during the early days following the accident, and all those who continued to live in contaminated areas received radiation doses from Chernobyl-released radionuclides that were relatively low and unlikely to lead to widespread and serious health effects." The doses to these individuals are comparable to those caused by naturally occurring radionuclides that produce a range of background levels routinely experienced by everyone on the planet.

Some notable regions of high background radiation exist in several countries that are caused by higher concentrations of natural radionuclides in beach sands or in soil or water. The Chernobyl exposures are not unlike these naturally occurring areas that are not associated with discernible radiation health effects.

But there was also a social tragedy—mainly caused by the fear of the radiation fallout from the unshielded accident (it should be recalled that Chernobyl did not have any containment to mitigate the consequences of the accident, in stark contrast to the standards in nuclear reactors worldwide). Such radiation away from the immediate site of the plant, though low, was measurable throughout most of the northern regions of the world. As a result, people reacted with understandable fear. For instance, the media hysteria in large parts of western Europe led to an estimated additional 40,000 abortions among married women during the post-Chernobyl months, all of which were the result of fear (IAEA 1996c). The radiation levels were never high enough to justify even one of those abortions. Some food supplies, many only showing a modest presence of radioactive substances, were often abandoned, and even drinking water was sometimes labeled hazardous for the local citizenry, based simply on fear.

The international conference summing up the consequences of the accident (IAEA 1996b) included a population survey on non-radiation related symptoms carried out in areas directly affected by the accident vs. those areas not directly affected. The populations in both areas suffered about the same fear of radiation. These results showed that the fear of radiation is not directly related to whether people are living in areas affected or not.

UNSCEAR reported those psychological traumas and other related effects attributable to the fear of radiation, indicating that "The Chernobyl accident is known to have had major effects that are not related to the radiation dose. They include effects brought on by anxiety…and distress…and are essentially unrelated to any actual radiation exposure" (UNSCEAR 2008b).

Tragically, the most undesirable consequence of the horrific accident at Chernobyl was the fear of radiation rather than the accident itself.

The Fukushima nuclear accident

The Fukushima accident, occurring on 11March 2011 in Japan, was triggered by an extremely large earthquake under the Pacific Ocean, which caused a tsunami-generated wall of water. The tsunami inundation high approached 33 m and the runup high was up to 39 m, killing tens of thousands of people (IAEA 2015a). The Fukushima Daiichi site consisted of six nuclear power plants. At the time of the accident, Units 1, 2, and 3 were operating, but Units 4, 5, and 6 were in planned shutdown. The earthquake destroyed most electric power lines in the region, and the three operating plants lost their backup power supplies when the ensuing floods wiped out the internal electrical supply, including their standby diesel generators. The resulting loss of cooling to the three operating reactors led to core meltdowns and a sizable release of radioactive materials into the atmosphere, resulting in deposits on land and in the ocean.

Authorities mandated the evacuation and resettlement of some thousands of residents and imposed a relocation of them for, in some cases, several years. The result was serious detrimental effects to those people, including the death of some of the most vulnerable. But NONE of these impacts were the result of radiation exposure. The radiation levels were just too small.

The assessment of the Fukushima accident undertaken by the IAEA revealed that "doses incurred by members of the public were low and generally comparable with the range of effective doses incurred due to global levels of natural background radiation." Unsurprisingly, it concluded that "no early radiation-induced health effects were observed among workers or members of the public that could be attributed to the accident." This conclusion agreed with the UNSCEAR assessment that "no discernible increased incidence of radiation-related health effects is expected among exposed members of the public and their descendants" (IAEA 2015b).

UNSCEAR estimated that "The most important health effect [from the accident] is on mental and social well-being, related to the enormous impact of the earthquake, tsunami and nuclear accident, and the fear and stigma related to the perceived risk of exposure to ionizing radiation" (UNSCEAR 2014). Similar conclusions and lessons were reported by an ICRP Task Group (Gonzalez et al. 2013).

Again, the fear of radiation has been a major culprit in the Fukushima consequences.

Global nuclear power advances

The advent of nuclear power, starting with the first employment of commercial nuclear power in the 1960s, now provides approximately 10% of the world's electricity. It is generally recognized by responsible long-term planners that the global needs for electricity will continue to climb—especially as the push for the electrification of the transportation industry matures. But the fear of "anything nuclear" is impeding the social licensing of nuclear programs—mainly because of fear of radiation.

Nuclear waste cleanup

One of the issues that concerns many about the acceptability of nuclear power is the question of what to do with the so-called "nuclear waste;" namely, radioactive used nuclear fuel removed from the reactor once its useful lifetime to generate power is over. First, we need to recognize that about 96% of this "waste" is not waste at all. It can be converted to useful nuclear fuel since it is comprised mostly of uranium or plutonium. Many countries have declared that this is not a "waste" but rather an "asset" to be preserved.

Unfortunately, the current regulations for the design of an underground nuclear waste repository in the United States require the radiation level at the surface of such a repository to be less than 0.15 mSv y^{-1} for the first 10,000 y after repository closure, which is about 20 times less than natural background. This absurd restriction, based on the unnecessary fear engendered by radiation, makes it almost impossible to design and build a nuclear waste repository.

Myriad of benefits from radiation as a by-product of nuclear energy

Another factor generally unknown to the general public relates to the myriad of services and products that radiation technology has provided to modern life. An early book addressing this topic (Waltar 2004) summarized the enormous contributions that radiation technology is already providing in the fields of medicine, agriculture, modern industry, transportation, space exploration, combating terrorism and crime, arts and sciences, and environmental protection. This work has been expanded considerably and documented in the recent Elsevier encyclopedia on nuclear energy (Greenspan 2021), which contains 26 chapters in the Section titled "The Medical, Agricultural, and Industrial Applications of Nuclear Technology." This section is focused on these highly beneficial contributions to our global society. Already, the value of these contributions well exceeds that of the commercial nuclear power industry—both in terms of jobs and the economy. Yet there are still people who will not submit to a computerized tomography (CT) scan because of radiation fear, even though the science clearly shows that the benefits far outweigh the risks (McCollough 2018). There appears to be no end in sight for the further advancement of such radiation technologies, but only if the unsubstantiated fear of low-level radiation can be curbed.

CONCLUSION

This article has described views on the health effects attributable to radiation exposure situations involving low-dose, low dose-rate, and low dose-rate changes, taking into consideration the principal scientific professions studying this topic; namely, radiation pathology, radiation epidemiology, radiation biology, and radiation protection. Its goal has been to present an overview of the scientific evidence gained over the past half century that provides sufficient assurance that there is no valid reason to fear low levels of radiation exposure.

The current approach that is most used to guide regulators in protecting the general public from radiation exposure is referred to as Linear No-Threshold (LNT). It is currently deeply embedded in the international radiation regulatory system, yet it is understood very differently by the various professions involved, some as a premise, some as a hypothesis, and some as a practical model. As a result, the appropriateness of how it is used is highly debated. Because LNT has been understood by many as implying that radiation at any level, even down to zero, can potentially be interpreted to be a killer of people and potentially many people over space and time if they are exposed to even infinitely small levels of radiation, it is no wonder that many members of the public and their policy-makers are still fearful of the word “radiation.”

Most policy makers will agree that endeavors involving radiation have major benefits (e.g., medical, agricultural, and industrial applications) if their radiation exposure can be properly harnessed, but it can be harmful if uncontrolled. There is solid agreement among the full radiation health community that unrestricted radiation exposure at high levels is dangerous for individuals and clearly should be prevented. There is also solid agreement that exposure at medium levels can increase the normal incidence of health effects associated with radiation (such as malignancies, which cannot be attributed individually but only collectively) and should also be limited.

But regarding low level radiation, the conundrum is that the effects, either detrimental or beneficial, if any, are *from the clinical perspective* very small and difficult to be evidenced. Any radiation health effects at low dose, if they exist at all, are almost always dwarfed by other toxins that we live with every day, such as the natural bodily burning of oxygen so essential to life.

An erred interpretation of the LNT radiation protection model feeds directly into public fears. Unfortunately, such unsubstantiated fear is not without consequences. Such fear has already caused detrimental effects on frightened people. Moreover, it is seriously restricting the use of radiation technology in the fields of medicine, agriculture, modern industry, and energy. With the ever-growing need to lift billions of our fellow citizens out of poverty and provide them with ready access to the advances necessary to experience a higher quality of life, the unsubstantiated fear of radiation is becoming a matter of severe ethical consideration.

Enormous progress can and should be made by encouraging radiation regulatory bodies to recognize the shortcomings of the presently interpreted and applied regulation of low-dose radiation exposure situations and the need to revisit it—allowing them to take into account the fact that radiation damage (if any) at low levels is essentially insignificant. The most significant contribution of such regulatory agencies would be to employ their work in a manner clearly demonstrating to a cautious and suspecting public that low levels of radiation are simply not to be feared. We live in an atmosphere of such radiation every day of our lives and should not be alarmed when small amounts of additional radiation exposure, usually similar to the variations in background natural exposure, are introduced into our environment.

In conclusion, there is a clear scientific basis for removing the unnecessary and debilitating fear of low-level radiation. Once this conclusion is accepted by a presently confused public, enormous progress in harnessing radiation processes can be achieved to bring into being the benefits desired by our growing global humanity.

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