

An Evolved System of Radiological Protection

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Abstract. The current system of radiological protection based on the Linear No-Threshold (LNT) hypothesis has greatly contributed to the minimization of doses received by workers and members of the public. However, it has brought about “radiophobia” among people and waste of resources due to over-regulation, because the LNT implies that radiation is harmful no matter how small the dose is. The author reviewed the results of research on health effects of radiation including major epidemiological studies on radiation workers and found no clear evidence of deleterious health effects from radiation exposures below the current maximum dose limits (50 mSv/y for workers and 5 mSv/y for members of the public), which have been adopted worldwide in the second half of the 20th century. Now that the existence of bio-defensive mechanisms such as DNA repair, apoptosis and adaptive response are well recognized, the linearity assumption cannot be said to be “scientific”. Evidences increasingly imply that there are threshold effects in risk of radiation. A concept of “practical” thresholds or “virtually safe doses” will have to be introduced into the new system of radiological protection in order to resolve the low dose issues. “Practical” thresholds may be defined as dose levels below which induction of detectable radiogenic cancers or hereditary effects are not expected. If any workers and members of the public do not gain benefits from being exposed, excepting intentional irradiation for medical purposes, their radiation exposures should be kept below “practical” thresholds. On the assumption that the current dose limits are below “practical” thresholds and with no “radiation detriments”, there is no need of “justification” and “optimization” (ALARA) principles for occupational and public exposures. Then the ethical issue of “justification” to allow benefit to society to offset radiation detriments to individuals can be resolved. And also the ethical issue of “optimization” to exchange health or safety for economical gain can be resolved. Only this approach — introduction of the concept of practical thresholds — can make the system of radiological protection be based on an individual-oriented philosophy and satisfies the egalitarian principle of ethics in the 21st century.

1. Introduction

How to secure necessary energy for the future is our big problem to be solved. As developing countries need tremendous amount of energy for their modernization, environmental issues such as global warming and acid rains are increasingly serious in the 21st century. Nuclear power does not emit attributable gases such as carbon dioxide and sulfur oxides, and now it is the only “safe, economic and practical” alternative to the dangerous methods of electricity generation by burning fossil fuels.

Catastrophic reactor accidents such as the Chernobyl can be prevented by human wisdom. Disposal of radioactive wastes will no longer be a problem difficult to be solved, if people don’t have unnecessary fear of radiation after being familiar with the truth about the health effects of radiation in small quantities.

The Linear No-Threshold (LNT) hypothesis, implying that radiation is harmful even in extremely small quantities, has greatly contributed to the minimization of doses received by workers and members of the public. On the other hand the LNT hypothesis has brought about “radiophobia” among people and waste of resources due to over-regulation. The hypothesis is now becoming a deathblow to the uses of radiation and nuclear power.

In this paper the author is going to make proposals for an evolved and simplified system of radiological protection in view of the current knowledge about low-level radiation health effects.

2. Current philosophy of radiological protection

Throughout the hundred-year history of the uses of ionizing radiation in medicine and industry there has been advice on the need to protect people from the hazards associated with exposure. Protection standards have evolved throughout this period to reflect both the scientific understanding of the biological effects of exposure, and social and ethical standards to be applied.

2.1. Current classification of radiation health effects

The International Commission on Radiological Protection (ICRP) classifies harmful radiation health effects to be protected against into two types, “deterministic” effects with thresholds and “stochastic” effects without thresholds [1]. “Deterministic” effects are those for which both the probability and severity of the effect vary with the dose, and for which a threshold of dose-response may occur. In contrast, “stochastic” effects are those for which only the probability of the occurrence of effect, and not its severity, is regarded as a function of dose, without threshold.

2.2. Current system of radiological protection

The aim of radiation protection should be to prevent deterministic effects and to limit the probability of stochastic effects to levels deemed to be acceptable. The ICRP recommends the following general principles [1].

- 1) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (Justification of a practice)
- 2) All exposures should be kept as low as reasonably achievable, economic and social factors being taken into account. (Optimization of protection, ALARA principle)
- 3) The exposure of individuals should be subject to dose limits. (Individual dose and risk limits)

2.3. Preparation of the next ICRP Recommendations

The ICRP has been encouraging discussion, during the past few years, on the way of expressing radiological protection philosophy in its next Recommendations, which it plans to publish in 2005. The ICRP is now considering a revised, simpler approach that is based on an individual-oriented philosophy and represents a potential shift by the Commission from the past emphasis on societal-oriented criteria.

In spite of the great efforts of Prof. Roger Clarke, Chairman of the ICRP, to make its Recommendations simpler and more understandable, his original progressive proposal of “controllable dose” seems to have been retracted after open discussions with so many ‘conservative’ radiation protection experts [2, 3, 4]. Consequently shortcomings of LNT- based system will not be corrected and the people’s anxiety about radiation will not be lessened.

3. The advantages and disadvantages of LNT hypothesis

3.1. The advantages of LNT

Owing to the assumed additivity of radiation doses the LNT hypothesis simplifies exposure dose control and recording in radiation protection. Another merit of the hypothesis is that it can give people an incentive of exposure reduction because it implies that any radiation dose, no matter how small, can result in detrimental health effects, such as cancer and genetic damage.

3.2. The disadvantages of LNT

3.2.1. Creation of “radiophobia”

The assumption that radiation is harmful at all levels of dose has been regarded as a proven scientific fact by public opinion, mass media, regulatory agencies and many scientists, and has brought about “radiophobia” among people.

In the former Soviet Union after the Chernobyl Accident a specially created commission consisting of newly-chosen, non-professional radiation protection “experts” politically reduced the relocation criteria from 350 mSv lifetime (5 mSv/y) to 70 mSv lifetime (1 mSv/y). Consequently, millions of people were falsely identified as the major victims of the accident, which evoked worldwide concern and played an important role in limiting the development of nuclear power in a number of countries [5]. Also, it has long been known that many people in the world have lifetime doses from background of more than 350 mSv with no indication of radiation harm.

The criticality accident occurred at the JCO nuclear fuel processing plant in Tokai-mura, Japan on September 30, 1999 caused psychological uneasiness of people around the plant and a tremendous amount of economic damage due to rumors, although most of the nearby inhabitants received only such minute doses of radiation as less than 1 mSv. Fear of radiation has proved to be more harmful to public health than radiation itself.

3.2.2. Unacceptability of dose limits

The major policy implication of a non-threshold relationship for stochastic effects is that some finite risk must be accepted at any level of protection. Then dose limits have to be based on “**acceptable risks**” under the LNT hypothesis. However, “acceptable risks” are not accepted by all the people. Risk is inherently subjective and there is no such thing as real risk or objective risk. Personal risk is inseparably connected to a person’s subjective view of life.

Both workers and members of the public do not receive direct benefits from radiation exposures excepting intentional irradiation for medical purposes. Therefore it is natural for them to ask for “**zero dose**” if even the smallest dose of radiation incurs any health risks. Given the linear, no-threshold hypothesis and ALARA, no dose is automatically ethically acceptable [6].

Regulators are apt to misunderstand that **the lower the dose limits, the more reassured** people may feel. Lowering dose limits will rather increase anxiety about radiation. **No matter how successful** radiation facilities are in lowering their radiation levels, the public can **never be completely satisfied and feel reassured**.

3.2.3. Waste of resources

The LNT hypothesis is often said to be a reasonable working assumption in radiological protection. However, people and even “reasonable” people are not always reasonable. If a radiation worker has developed a cancer, he or his wife is apt to think that his cancer might have been caused by radiation exposure at work. An application for Workmen’s Compensation or a lawsuit may be filed on the ground of greater than zero probability of causation (PC), no matter how small the dose is.

The LNT hypothesis will bring about endless over-regulation and waste of human and natural resources to take over-protective actions against radiation. The expenditure of large sums of money with no known public health benefit is not a conservative health policy.

4. Reappraisal of the biological basis of the ICRP’s policy

4.1. Radiation health hazards

Before the 1950’s, the main objective of radiation protection was to **avoid** such biological harm as skin erythema or malfunctioning of the bloodforming organs (nonstochastic or deterministic effects) that would inevitably follow high doses of ionizing radiation.

From the mid-1950's the interest has been focused on effects like cancer and hereditary harm (stochastic effects), for which no threshold doses have been established. Since it is assumed that the stochastic effects may be caused by any small radiation dose, no radiation dose can be called absolutely **“safe”**. On this basis, the aim of radiation protection has become to **prevent** non-stochastic (deterministic) harmful effects and to **reduce** the probability of the stochastic effects as far as “reasonably achievable”.

However, Dr. Lauriston Taylor, an emeritus member of the Main Commission of the ICRP, wrote in 1980: “**No one** has been **identifiably injured** by radiation while working within the first numerical standards set by the NCRP and then the ICRP in 1934” [7].

4.2. Threshold or no-threshold

The ICRP classifies harmful radiation effects into two types, deterministic effects with thresholds and stochastic effects without thresholds. For deterministic effects, the ICRP adopts **clinically observable** thresholds. However, the ICRP discusses only ‘**a real threshold**’ for stochastic effects and says: “there can be a real threshold in the dose-response relationship for those types of cancer only if the defense mechanisms are totally successful at small doses” (ICRP 60, paragraph 68).

A malignant transformation of a single cell is **not synonymous** with a tumor or cancer. Tumor formation requires several cell divisions and genome multiplications and the eventual outcome of such iterative processes are fundamentally unpredictable. The contribution of radiation to a malignant cell transformation is not a stochastic effect but a **highly conditional** one. Cancer induction is such a complex matter that it almost certainly **cannot be** adequately described by a **simple linear model** [8].

Radiogenic skin cancer experiments with pigs indicate that the malignancy of a tumor may be dependent upon the size of the dose. The **latency times** are also usually shortened when the dose is increased. If doses were low enough, the latent period might exceed natural lifetime.

The existence of threshold doses can seldom be proven. The difficulties in discerning threshold doses or concentrations depend probably to a great extent on the **variation in sensitivity** to the actual agent among the individuals. In the report on nonstochastic (deterministic) effects of ionizing radiation [9], the term **threshold dose** is used to denote the amount of radiation that is required to cause a particular effect in at least 1-5 per cent of exposed individuals. In the case of erythema of the skin, for example, the threshold dose is about 6-8 Gy received in a single exposure.

There seems to be **no rational** of distinguishing cancer risk assessments from those applied to other hazards, so called deterministic effects.

4.3. Effective dose vs. critical organ concept

Until 1977 and the adoption of Publication 26 [10], the recommendations of the ICRP were based on the **critical organ** concept. To prevent nonstochastic effects and limit stochastic effects, the ICRP revised the basis for its recommendations to take into account the total risk to the individual and introduced **effective dose** (equivalent).

Effective dose was first envisaged as a tool in planning and controlling the risk to radiation workers and to the public collaterally exposed. However, it is often misused to predict consequences. It is uncertain and quite variable quantity depending on the models and parameters used. Then the global average annual natural background effective dose of **2.4 mSv** is not a **stable reference**.

On the other hand, the use of the critical organ concept for internal emitter standards has a number of benefits. It is a relatively simple approach, and it lends itself to straightforward methods for controlling and monitoring exposures. These include the estimation of organ and body burdens using bioassay and *in vivo* counting techniques. It is not clear that any great benefits will be achieved over

the ICRP weighting factor approach unless the quality of risk estimates is improved [11].

4.4. Some findings about low dose radiation health effects

4.4.1. Hereditary effects

The 40-year follow-up studies on the genetic effects of atomic bomb radiation of Hiroshima-Nagasaki have demonstrated that there is **no statistically significant effect** of parental exposure to radiation of **0.4 to 0.6 Gy** on any of the genetic indicators studied [12].

4.4.2. Cancer-causing effects

(a) According to the report of the experts' group of OECD/NEA, **200 mSv** is the smallest dose for which a statistically significant radiogenic risk has been observed in the Life Span Study on Hiroshima- Nagasaki atomic bomb survivors [13].

(b) Under acute irradiation conditions, "**non-tumor doses**", the highest doses at which no significant increase of tumors were observed above the control level (Dr. Hiroshi Tanooka), were greater than 0.1 Gy for low-LET radiations and greater than 0.01 Gy for high-LET radiations. Under low dose-rate, chronic or partial body exposure conditions, "non-tumor doses" were much higher than the doses above [14].

(c) Although there are high radiation areas exceeding 10 mSv/y in India, Brazil and Iran, there is no evidence that natural radiations are causing adverse health effects among the inhabitants [15].

(d) The second analysis of mortality of Japanese nuclear industry workers concludes that the results have not yielded any definite evidence as to whether exposure to occupational low-level radiation increases cancer mortality [16].

(e) The final report of the large study of **United States nuclear shipyard workers** funded by the US Department of Energy showed that there was significantly lower total mortality in the exposed groups (both the < 5 mSv and ≥ 5 mSv groups) than in the non-radiation workers who engaged in similar work [17, 18]. However, NCRP Report No. 136 discarded all of the data of this study on the basis of an undocumented flaw in selecting nuclear workers [19].

(f) The large combined study of nearly 96,000 United States, United Kingdom and Canadian nuclear workers showed no excess (negative) risk of total cancer mortality. Assuming that radiation cannot be beneficial, the study purports to show a statistically significant dose response trend in leukemia mortality (one sided P value=0.046), but it was based largely on a few cases with cumulative doses above 400 mSv who worked at a reprocessing plant at which there could have been exposures to chemicals [20].

(g) The 100 years of observation on **British radiologists** revealed no statistically significant increase in cancer mortality among radiologists who first registered after 1920 compared to other male physicians in England. Their mortality was significantly lower than that of all male medical practitioners. Moreover, there was no evidence of an effect of radiation on diseases other than cancer even in the earliest radiologists whose average lifetime dose was estimated to be 20 Sv [21].

In addition the longevity of the earliest radiologists (1897-1920) was slightly longer than other male medical practitioners [22]. The longevity data from the British radiologists study indicate that the dose limit recommended for radiation workers by the ICRP in 1934 of 0.2 r /day (about 50 rads /year) did not need to be lowered [23].

5. Proposal of an evolved system of radiological protection

5.1 Requirements for a new system of radiological protection

5.1.1. The system shall be based on sound science

Now that the existence of bio-defensive mechanisms such as DNA repair, apoptosis, adaptive response and immune system are well recognized, the linearity assumption at all dose levels can be said “unscientific”. There are an abundance of data in low dose radiation health effects contradictory to the LNT hypothesis, including biologically beneficial “hormesis” [24, 25, 26, 27]. Evidences increasingly imply that there are threshold effects in risk of radiation [12].

In the 13 February 2003 edition of the Journal “Nature” Prof. E. J. Calabrese and L. A. Baldwin of Univ. of Massachusetts commented on their belief that the most fundamental shape of the dose response is neither threshold nor linear, but U-shaped (hormetic), and hence both current models, especially the linearity model, provide less reliable estimates of low-dose risk [28].

A co-operative approach by Drs. Myron Pollycove and Ludwig E. Feinendegen to answer the questions on the quantitative and qualitative DNA damages from non-radiation sources, largely endogenous reactive oxygen species (ROS), and following exposure to low doses of ionizing radiation suggests that the LNT hypothesis is invalid for complex adaptive systems such as mammalian organisms [29].

The US Health Physics Society issued a position statement in 1996, in which the Society recommends against quantitative estimation of health risks below an individual dose of 5 rem (50 mSv) in one year or a lifetime dose of 10 rem in addition to background radiation, because below 10 rem, risks of health effects are either too small to be observed or are non-existent [30].

Since we do not have sufficient data to prove that low dose radiation is beneficial or harmful, it seems to be scientific to assume a “**truncated**” model of radiation risks for radiation protection purpose.

5.1.2. The system shall be coordinated with that of other “hazardous” substances

New systems can be coordinated with other health hazards such as ultra-violet rays and toxic chemicals, if we consider that ionizing radiations are no exception of the maxim of Paracelsus (1493-1541) below, which has been a dogma in toxicology up to now.

**“All substances are poisons, there is none which is not a poison.
The right dose differentiates a poison from a remedy.”**

As for chemicals, emphasis has been shifted from “hazard” management to prevent acute toxicity to “risk” management to minimize adverse health effects due to prolonged exposure to low concentrations. However, Prof. Osamu Wada, a toxicologist, emphasizes the importance of hazard assessment rather than risk assessment in which regulatory agencies intend to minimize risks by taking a large safety margin into consideration. He intends to release people’s anxiety and fear for “dioxin” by sound science and maintains that assessment of human hazard should be based on medical evaluation of human data. In the case of dioxin with human experience of more than 340,000 exposed people, hazard assessment is possible and minimum hazardous dose can be determined by the dose-response relationship in humans [31].

Without human data, protection criteria for both chemicals and ionizing radiations have to be set by risk assessment based on animal experiments. If we have human data, however, protection standards should be based on **actual hazard not on hypothetical risk**.

5.1.3. The system shall be easily understood and make sense

The idea that substances that are poisonous in large quantities may be harmless or beneficial (essential) to the human health in small quantities is more commonsense and understandable to ordinary people. All of the essential trace elements in our diet have that characteristic. It has been

suggested that ionizing radiation may be an essential trace energy [32]. The hypothesis that radiation is harmful no matter how small the dose does not make sense when you consider that every human has billions of their cells hit by radiation from natural radioactivity in their body each day. As early life born about four billion years ago was exposed to nearly ten times current natural radiation dose rates, modern organisms may be more resistant to the adverse effects of radiation because mutation repair mechanisms evolved under higher radiation levels [33].

Prof. Roger Clarke says in his paper [2], “It is true that, increasingly, science is judged in the courts rather than by national academies of science. Judge and jury are increasingly likely to decide the issue and it is they who must be convinced as to whether there is a threshold and thus no risks at low doses of radiation.”

Ordinary adult members of the public understand the statement “Low doses of radiation are safe”. They do not understand comparative risk. All they want to know is if radiation is safe or not. They know that nothing is absolutely safe and they don’t expect anything to be [34].

5.2 The aim of radiological protection

The aim of radiological protection should be **not to harm anyone**. In order to achieve this objective, radiation exposures of people shall be maintained below **“practical” threshold doses**.

5.2.1. Introduction of “practical” threshold

(a) A concept of **“practical” thresholds** is introduced and the classification of stochastic and deterministic radiation effects are no longer used. Radiation induced cancer and hereditary effects are assumed to have relevant “practical” threshold doses. A “practical” threshold is a level of exposure below which induction of **detectable** radiogenic cancers or hereditary effects is not expected. According to Dr. Zbigniew Jaworowski, the Polish representative to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the practical threshold to be proposed could be based on epidemiological data from exposures in medicine, the nuclear industry, and regions with high natural radiation [35].

(b) The ICRP discusses only **“a real threshold”**, however, what we need in practical radiation protection is **“virtually safe dose”**. Regardless of the debate over whether there are thresholds or not for stochastic effects, **the public should be aware that there are practical thresholds** for radiation induced adverse health effects.

(c) We must be more careful in our use of the word **“risk”**. The concept of “zero risk” is and will continue to be an ontological construction that lacks reality. One possibility of dealing with the problem is to put a limit to what we mean by a risk at a **“non-dominant”** dose or concentration, i.e. at a dose (concentration), which, even in a conservative estimation, does not involve any harm that can be proven, which we, therefore, **cannot maintain will harm anyone**. We give radiation protection a scientifically justifiable basis [8].

5.2.2. Implications of “practical” threshold

As any workers and members of the public do not gain benefits from radiation exposures excepting intentional irradiation for medical purposes, their radiation doses should be kept below “practical” thresholds.

There is **no need of “justification” and “optimization” (ALARA) principles** for radiation protection against normal non-medical exposures, because there assumed to be no “radiation detriments” as far as exposures are maintained below “practical” thresholds. Accordingly the ethical issue of “justification” to allow benefit to society to offset radiation detriments to individuals can be resolved. And also the ethical issue of “optimization” to exchange health or safety for economical

gain can be resolved [36, 37, 38]. Only this approach — introduction of the concept of “practical” thresholds — can be said to be based on an **individual-oriented philosophy** and satisfies the **egalitarian principle of ethics**.

5.3. Proposed dose limits

- **Worker : 50 mGy/y (500 mGy/y for partial body or single organ exposure)**
- **Public : 5 mGy/y (50 mGy/y for partial body or single organ exposure)**

- **In case of high LET-radiations such as alpha particles and neutrons, the above dose limits should be multiplied by 1 /10.**

(a) There seems to be **no clear evidence** of deleterious health effects from radiation exposures at the current dose limits (50 mSv/y for workers and 5 mSv/y for members of the public), which have been adopted worldwide in the second half of the 20th century. Those dose limits are assumed to have been set below certain “practical” thresholds.

(b) **“Absorbed dose”** should be ‘principal quantity’ in the field of radiological protection and used for measurement and control of radiation. **“Effective dose”** is not used because quantitative risk assessments are not required for exposures below “practical” thresholds. ICRP risk coefficients derived from large doses are said to be unsound and meaningless when applied in routine radiation protection [39].

(c) In the white paper on “controllable dose”, the US Health Physics Society says, “The HPS believes the most important aspect in achieving this goal is a risk-informed, dose-based system with **elimination of quantified risk estimates and risk-based terminology** at occupational and environmental dose levels” [40].

(d) **Dose constraints** should be used whenever they are necessary to comply with the relevant dose limits. Dose constraints are ‘dose objectives’ for (prospective) planning purposes under specific exposure conditions and may be sometimes apportioned dose limits among several radiation sources.

(e) Reduction of **collective dose** should not be the objective of occupational radiation protection, but rather be the results of the efforts to keep the doses of the most exposed workers below the dose constraint and the optimum uses of total workforce. It is well-known that individual doses in a group have a lognormal distribution, the mean annual value being an order of magnitude less than the dose limit.

5.4. Bands of concern

The proposed dose limits may be most appropriate to be positioned in the 2nd Band of concern in the Table below.

Table Bands of concern about individual whole body doses in a year

Band of Concern	Description	Level of Dose* (mGy /y)	Protective Actions
Band 3	High (Serious)	> 100	Justify the exposure
Band 2	Low (Normal)	1 – 100 (Natural background radiation)	(Administrative dose limits) Worker: 50 mGy/y Public: 5 mGy/y
Band 1	Very Low (Negligible)	< 1	No protective action

* Whole body low-LET radiation

6. Conclusion

At the start of the 21st century, the most important task is to demonstrate that workers and members of the public have been adequately protected by the dose limits adopted worldwide in the second half of the 20th century.

Radiation protection professionals do not need to convince scientists; they need to convince ordinary citizens who are afraid and worried and who want to judge and decide for themselves. Radiation protection has increasingly become a public science, a science only effective when it is accepted by those it intends to protect [41]. We must not let radiation protection become a health hazard [8].

As present radiation protection standards are said to be based to a large extent on data that have been forced to conform with the LNT model [42], it is essential to reevaluate the accumulated scientific data without preconception of the LNT hypothesis.

The author believes that the introduction of a “practical” threshold concept as proposed in this paper will be essential for the evolved system of radiological protection, simple and understandable. Only this approach can make the system be based on an individual-oriented philosophy and satisfies the egalitarian principle of ethics in the 21st century.

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