Position Paper

ENISS members' view regarding the Linear-Non-Threshold-Hypothesis (LNT)

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CONTENTS

SUMMARY

This position paper examines the interpretation and application of the Linear-Non-Threshold (LNT) hypothesis in radiological protection. While the LNT model has historically underpinned international standards, its extrapolation to very low doses can lead to misconceptions and unintended consequences in both public perception and regulatory practice.

This paper also brings arguments to support an appropriate and balanced application of the Linear-Non-Threshold (LNT) hypothesis.

The following key considerations summarise the position:

1. The Linear-Non-Threshold (LNT) hypothesis has progressively been interpreted in the way that any dose, even very small ones, could cause cancer, forgetting that the linear relationship at low doses remains a hypothesis and an extrapolation from higher doses. This interpretation of the LNT hypothesis tends to feed an irrational fear of low radiation in the public.
2. An unreasonable application of the LNT hypothesis leads to overdesigned radiation protection measures resulting in a costly strife for minimisation down to zero dose.
3. In decision-making processes relating to radiation protection in nuclear installations, generally based on optimisation approaches, the LNT hypothesis and its limitations must be well understood.
4. The Radiation Protection System should stress the message that being below the regulatory dose limits and reasonably optimised provides an adequate level of protection.

Definitions of low and very low doses can be found in [1]:

Terminology for dose bands	*Range of absorbed dose for low-LET radiation[a, b]*	*Scenarios*
High	Greater than about 1 Gy	Typical dose (whole or partial body) to individuals after severe radiation accidents or from radiotherapy
Moderate	About 100 mGy to about 1 Gy	Doses to about 100,000 of the recovery operation workers after the Chernobyl accident (annex D [U14])
Low	About 10 to about 100 mGy[c]	Dose to an individual from multiple whole-body computerized tomography (CT) scans
Very low	Less than about 10 mGy	Dose to an individual dose from conventional radiology (i.e. without CT or fluoroscopy)

1. ORIGIN OF LNT MODEL AND ITS VALIDITY

The Linear-Non-Threshold (LNT) model is a concept used in radiation protection to estimate the risk of cancer induction from exposure to ionising radiation.

The LNT model suggests that there is no threshold dose below which radiation poses no risk; instead, it is considered that the risk of cancer increases linearly with dose, even at low and very low levels[1]. The LNT model indicates that every exposure to ionising radiation, no matter how small, carries some risk of causing mutations that may lead to cancer.

However, the validity of the LNT model is still a topic of debate within the scientific community. The Health Physics Journal has recently devoted a special edition exclusively to this topic, inviting scientists and researchers with varying opinions on LNT and its applications [2].

Some researchers claim that the LNT assumption is suitable to fit data from epidemiological low dose studies [3], while others argue that there may be a threshold below which radiation exposure is harmless or even beneficial according to a phenomenon known as hormesis [4]. Studies of natural background radiation effects suggest an absence of harmful effects at low doses, e.g. [5]. Reference [6] shows that biological effects of low-dose radiation are more complex than the simple LNT model suggests.

UNSCEAR *(The United Nations Scientific Committee on the Effects of Atomic Radiation)* has suggested five plausible dose-response relationships for the risk of cancer in the ranges very low, low and moderate doses, illustrated in Figure 1 [1].

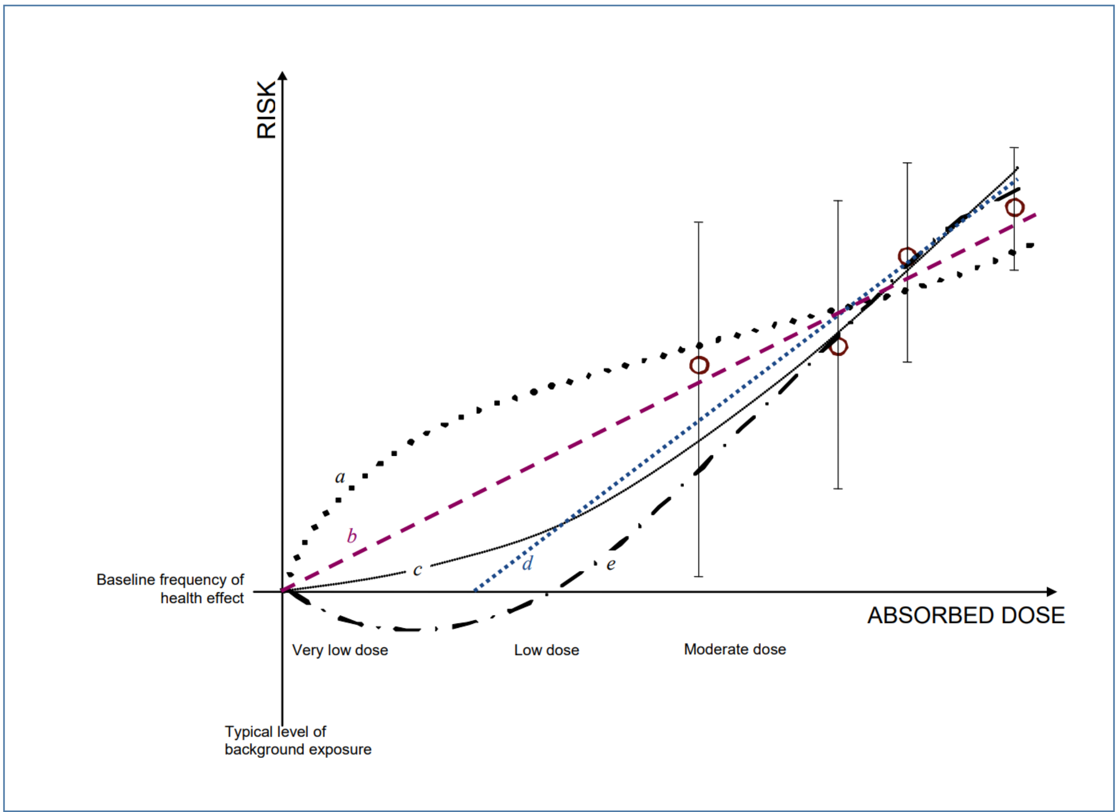

Figure 1 *(from [1])*

[1] See definitions on page 3.

The data points and confidence intervals marked on the graph represent observations of increased frequency of occurrence of a specific cancer type in populations exposed to moderate doses. The various lines represent the following plausible dose–response relationships for inferred risk of cancer for exposures in the ranges of low and very low doses:

(a) supralinear;
(b) linear nonthreshold (LNT);
(c) linear–quadratic;
(d) threshold;
(e) hormetic.

The Health Physics Society (HPS) has also recently issued a series of 22 videos explaining the history of LNT where the following steps are proposed [7]:

- *"Re-examine the current regulatory and cancer risk models – replacing the most fundamental assumption (that any increase in dose is an increase in risk) with a true null hypothesis (that there is no effect);*
- *Work toward an understanding of the low dose response using an integration of evolutionary biology principles and current epidemiological research findings;*
- *Re-evaluate the regulatory paradigm of "as low as reasonably achievable" (ALARA) to determine its merit on a scientific basis; and*
- *Harmonize radiation protection by considering all dose response models and applying the LNT model only to the point where adverse health effects are observed (e.g. above 100 mSv or 50 mSv y^{-1})".*

ENISS members see value in the ongoing debate and believe it could be a constructive step forward.

The origin of the LNT model can be traced back to Hermann J. Muller, who conducted experiments with fruit flies (Drosophila melanogaster) in the 1920s and 1930s. Muller's research demonstrated that ionising radiation could induce mutations in fruit flies, leading to genetic changes and abnormalities in subsequent generations. His work provided early evidence suggesting that radiation-induced damage to DNA could lead to heritable genetic mutations and contributed to the development of the LNT model. However, the study that can be seen as foundational for the LNT model had been done at radiation levels several orders of magnitude above the natural background. In addition, the existence of repair processes was not known at that time.

Later studies, including those conducted during the Manhattan Project, have suggested the existence of a threshold below which radiation exposure may not cause significant harm [7]. The Manhattan Project, which aimed to develop nuclear weapons during World War II, involved extensive research on the health effects of radiation exposure, including studies with laboratory animals such as mice. Some of these studies indicated that there might be a threshold dose below which radiation-induced health effects, particularly cancer, were not observed or were significantly reduced. These findings challenged the assumption of linear extrapolation of risk from high to low doses and thus the LNT model.

Recent assessments of existing studies show, however, confirmation of the adequacy of considering the LNT hypothesis [17].

The LNT model in the low dose range is an assumption and its validity is still a topic of debate within the scientific community and amongst various organisations.

2. LNT AND EPIDEMIOLOGICAL STUDIES

We are faced with the problem that there are epidemiological studies that show radiation effects for moderate doses around 100 mGy, notably the Life Span Study (LSS) about the atomic bomb survivors in Hiroshima and Nagasaki. But despite recent studies, such as the International Nuclear Workers Study (INWORKS), the sufficiency of evidence of the LNT relationship still seems to be questionable. For instance, at low and very low doses, it is difficult or even impossible to find populations that differ in their radiation dose only. An assessment of epidemiological studies can be found in reference [10] and Reference [11] states: "*Due to large uncertainties, epidemiological studies have not provided consistent estimates of radiation risk for effective doses less than 100 mSv".*

The INWORKS is a large-scale epidemiological study that aims to assess the risk of cancer mortality associated with protracted low-dose exposure to ionising radiation among nuclear industry workers [12]. This study collects data on radiation doses in the low dose region received by workers during their employment in the nuclear industry, in the USA, the UK and France, and analyses the association between radiation exposure and cancer mortality rates. Our understanding from the INWORKS study is that it supports the LNT hypothesis, even at low doses, despite large uncertainties. Pooling data from multiple countries/areas with varying levels of background radiation and different patterns of medical exposure can present challenges in interpreting the results of epidemiological studies. These exposures differ significantly in the countries included in the INWORKS study and may be an order of magnitude higher than the average occupational exposure in the nuclear industry, which significantly adds uncertainty to the outcome of the study.

3. LNT AND FEAR OF RADIATION

The LNT model may be criticised for potentially fostering unjustified fear of radiation. This criticism may arise from several factors:

- Extrapolation to low doses: the LNT model suggests that there is no safe threshold for radiation exposure, and that even very low doses of radiation carry some risk of causing cancer. While this approach is adopted in radiation protection regulations to err on the side of caution, some argue that it may lead to an exaggerated perception of risk, particularly for low-dose exposures encountered in everyday life.
- Lack of context: according to the LNT model all dose-response relationships are assumed to linear, without considering factors such as dose rate, radiation quality, or individual susceptibility. This simplified approach does not account for the complex biological mechanisms involved in radiation-induced carcinogenesis. It simply provides a generalized relationship between exposure and risk. However, this simplification may contribute to a perception of radiation as uniformly harmful, regardless of context.

- Misinterpretation of risks: public perception of radiation risks can be influenced by media coverage, sensationalised stories and misinformation. The LNT model, with its emphasis on linear extrapolation of risk, may be misinterpreted as implying that any radiation exposure, no matter how small, poses a significant threat to health. This can contribute to an atmosphere of fear and anxiety surrounding radiation-related activities and technologies. Reference [8] argues that low-level radiation should not be feared and has given some arguments against the upcoming fear of radiation.
- Impact on policy and regulation: unreasonable use of radiation protection standards based on the LNT model may lead to overly conservative regulations, precautionary measures, and public health interventions. While the intention is to minimise potential risks, the implementation of stringent regulations without considering the absence of scientific evidence on low-dose radiation effects can fuel fear of radiation and hinder the beneficial use of radiation in medicine, industry, and research.

ENISS members share the view that the ICRP should promote a more balanced public perception of radiation risk, thereby preventing unjustified fear.

4. LNT AND ALARA

The LNT model coupled with the As Low As Reasonably Achievable (ALARA) principle can contribute to a narrative that emphasises minimising radiation exposure to the lowest possible level (meaning the lowest possible risk when applying the LNT model), sometimes leading to the perception that "the ideal level is no exposure at all".

As a reminder, the ALARA principle is a fundamental tenet of radiation protection that advocates reducing radiation exposure to the lowest reasonable levels, taking into account technical, economic, and societal factors. The goal is to keep radiation doses as low as reasonably achievable while still allowing for the conduct of necessary activities involving radiation.

When applied together, the LNT model and the ALARA principle result in a precautionary approach to radiation protection where efforts are made to minimise radiation exposure to the greatest extent possible, often erring on the side of caution. While the intention is to reduce potential risks associated with radiation exposure, this approach can sometimes lead to an emphasis on avoiding exposure altogether, even at levels where the risk of harm may be uncertain or even negligible.

An overly cautious stance towards radiation exposure may result in unnecessary restrictions on activities involving radiation, such as medical imaging procedures or nuclear power generation. Thus, a more balanced approach is needed, one that considers both the potential risks and benefits of radiation exposure and weighs them against other societal priorities and considerations.

Ultimately, the application of the LNT model and the ALARA principle in radiation protection requires careful consideration of scientific evidence, risk assessment, and societal values to ensure that regulatory decisions are both protective of public health and conducive to the advancement of beneficial applications of radiation technology.

5. LNT AND THE PRECAUTIONARY PRINCIPLE

The LNT model coupled with the precautionary principle may lead to a strife for minimization down to zero dose.

However, precautions should be applied in a reasonable and proportionate manner. The focus should not be on what is possible, but on what is reasonably achievable. Yet, in practical radiation protection, it is not uncommon to follow the approach of doing what is possible, regardless of the effort, manpower, or cost required.

The LNT hypothesis is generally applied to moderate doses but also to low and very low doses, and even infinitesimal doses. However, as already stated above, there are considerable uncertainties regarding the dose response in the low and very low dose regions.

A reasonable way of applying LNT, especially at low and very low doses, is needed to avoid misuse during optimisation and the tendency to continuously reduce doses (see reference [18] on optimization).

6. SUMMATION OF DOSES AND LNT

UNSCEAR [1] states that the sum of all doses is decisive for a radiation effect, which tends to justify the need to base epidemiologic studies at (very) low doses on the sum of all exposures, including natural background radiation.

The ICRP confirmed LNT in its basic radiation protection recommendations in Publication ICRP 103 [13] as follows:

“The central assumption of a linear dose-response relationship for the induction of cancer and heritable effects, according to which an increment in dose induces a proportional increment in risk even at low doses, continues to provide the basis for the summation of doses from external sources of radiation and from intakes of radionuclides”.

The summation of doses is generally recognised as a good practice, and this is an advantage for practical radiation protection. The possible summation of doses could have been simply postulated without any reference to LNT. How the dose-response curve is in reality, whether there is a threshold or not, does not matter to assuming that individual doses can be summed up for radiation protection purposes. Though, LNT is of practical interest to assess the health effects due to summation of doses.

The key question is probably not about the use or not of the LNT hypothesis, but about the need to explain how to deal with the summation of low and very low doses.

7. POSSIBLE PRACTICAL APPROACHES ACCOUNTING FOR THE LIMITATIONS OF THE LNT HYPOTHESIS

The average occupational individual dose in the nuclear industry is 1 mSv/y, in medicine 0.5 mSv/y and in industrial use 0.3 mSv/y [14].

One way to contextualise the occupational dose of 1 mSv is to compare it with natural background radiation levels. Background radiation varies widely depending on geographical location, but on average, it is typically in the range of 1-10 mSv per year[2]. An occupational dose of 1 mSv per year may then be considered comparable to background radiation levels.

Two practical approaches, which interest and practicality should be considered, are presented here for illustrative purposes:

<u>Traffic-light scheme</u>

A traffic-light scheme could serve as a helpful tool for communication and implementation of the radiation protection system.

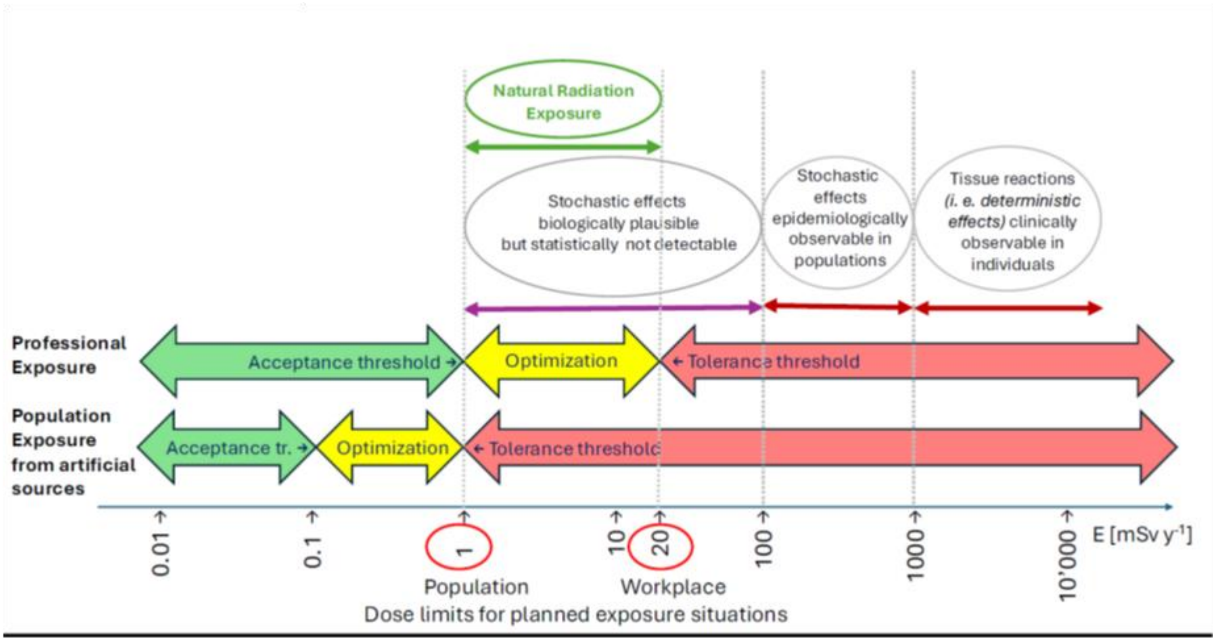

Figure 2 (Courtesy by H. Voelkle [15])

Such a scheme is easy to understand: exposures in the RED region are not acceptable and require protective action, in particular if limits are exceeded. In the YELLOW region, exposures are considered tolerable. It is the region of optimisation considering all relevant aspects. Exposures in the GREEN region are considered so low that the benefit gained by some formal dose reduction or optimisation measures rarely outweighs the cost or effort needed for these measures.

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[2] Humans have always been exposed to natural sources of radiation, with very different levels of exposure in different regions of the world. Several studies, e.g. [9], did not identify negative health effects due to high background radiation.

Cut-off values

Cut-off values could be introduced to support the optimisation process, stating for example that an occupational dose of 1 mSv/y and a public dose of 0.1 mSv/y should be seen as optimized. A similar proposal was made by Abelquist [16], asking the National Council on Radiation Protection and Measurement of the USA to increase the negligible individual dose to 0.1 mSv/y and define it as a stopping point for ALARA.

Irrespective of such a cut-off, basic radiation protection measures would be implemented in any case as part of the regulatory requirements and safety culture, such as shielding, restricting access to radiation protection areas, avoiding the uncontrolled spread of contaminations, making use of the distance law, restricting radioactive effluents, etc.

8. CONCLUSION

The scientific community continues to debate the validity of the LNT model and explore alternative dose-response models, such as hormesis, which suggests that low doses of radiation may have beneficial effects, or thresholds below which no harmful effects occur.

In decision-making processes relating to radiation protection in nuclear installations, generally based on optimisation approaches, the LNT hypothesis and its limitations must be well understood.

At very low doses, whatever the exposure context is, people and the environment are safe, and nobody should fear radiation at that level.

The narrative that "absence of evidence is not evidence of absence", which is often used to authenticate the LNT model at low and very low doses, should be changed into "non-discernible effects should not be treated as harmful and should not be exaggerated in regulatory frameworks".

The average occupational dose worldwide for all applications of ionising radiation, which is around 1 mSv or less [14], does indeed provide some context for evaluating radiation exposure levels. One could conclude that being below the regulatory dose limits and reasonably optimised provides an adequate level of protection.

ENISS members share the view that these considerations should be appropriately taken into account by the ICRP and the Radiation Protection Regulators.

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