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Regulatory implications of a linear non-threshold (LNT) dose-based risks

C.R. Aleta [1,2]

Lackierergasse 3/4, A1090, Vienna, Austria

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ABSTRACT

Current radiation protection regulatory limits are based on the linear non-threshold (LNT) theory using health data from atomic bombing survivors. Studies in recent years sparked debate on the validity of the theory, especially at low doses.

The present LNT overestimates radiation risks since the dosimetry included only acute gammas and neutrons; the role of other bomb-caused factors, e.g. fallout, induced radioactivity, thermal radiation (UVR), electromagnetic pulse (EMP), and blast, were excluded. Studies are proposed to improve the dose-response relationship.

1. Introduction

Almost all regulatory requirements authorizing activities that use ionizing radiation such as in industry, health, agriculture, and basic research, is based on the radiation protection concept that hinges on the acceptance of the linear non-threshold (LNT) theory. LNT implies that any dose, no matter how low, can pose risks for genetic (hereditary) defects or cause cancer.

LNT was derived using statistically significant dose-response (DR) relationship between radiation dose received by the survivors of the atomic bomb explosions in Hiroshima and Nagasaki and the observed health effects, mainly hereditary disorders and cancer. (Decades later, non-cancer risks are also derived from the same population.)

The DR was based on the observable significant clinical/deterministic effects that were seen on population exposed at high doses, from 0.2 Gy upwards. Below this dose, there were no observable effects seen on the population. Nevertheless, DR is assumed to be linear down to zero dose. The extrapolation to zero of the DR has not been supported by sufficient evidence/data in man to show its linearity at low doses. (Some studies supposedly showing linearity involved other sample population and other exposure conditions dissimilar to the experience of the bomb survivors.) However, this assumption has been accepted to be the conservative and most prudent approach to address the delayed effects of ionizing radiation, and to estimate health risks at low doses.

The LNT was adopted in 1959 as basis for radiation protection at low doses (<0.2 Gy). Prior to this date, there were already recommended exposure dose limits aimed at protecting radiation workers only—the limits were called various names such as "tolerance dose" or "maximum permissible dose". Changes were made later to include dose limits for the public and to revise dose limits for workers. The dose limits recommended in ICRP (1990) have almost remained the same in the latest recommendations made in ICRP (2007). Table 1 indicates the average natural background radiation and lists some of these limits given in the original units. (Equivalent units in millisieverts [mSv] and milliGray [mGy] are shown for comparison in the third column.)

From Table 1 the earlier dose limits implied *threshold levels* (e.g. tolerance dose), above which biological effects could be observed. The terminology was changed to *maximum permissible* dose, which was not yet based on a non-threshold hypothesis, but on the concept of a threshold with large uncertainty (Stone, 1952; Sugahara, 2006). The threshold concept was revisited later due to genetic studies by Mueller and the studies by Lewis (1957) on leukemia effects based on the atomic bomb survivors. Both studies indicated a linear model on health effects of ionizing radiation (ICRP, 1959). (It would be shown in later studies that the DR for leukemia seemed to have a better fit if there was a threshold.) (Little and Muirhead, 1996; Hoel and Li, 1998).

The LNT was accepted internationally, implying that genetic and somatic effects of low dose irradiation are based on mutation directly induced by ionizing radiation. There were however, no significant demonstrable data indicating this was the case for low dose exposure of man to ionizing radiation, being the region where most of the radiation practices—e.g. medical, industrial, power, research—fall. High doses have already been shown to cause significant health detriments.

E-mail address: carlito.aleta@chello.at

[1] Formerly with IAEA/TC, Vienna, Austria.

[2] Formerly Director, Philippine Nuclear Research Institute, Quezon City, Philippines.

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Table 1
Radiation limits for occupation workers and public.

Year	Values (original units)	Organization/agency remarks (Idaho State University, 2008)
	Background values: 2.4 mSv/yr from natural background and 1.2 mSv/yr from manmade sources	Average of 3.6 mSv/yr. Natural bgd exposures vary from 1–10 mSv/yr depending on location and other contributing factors.(UNSCEAR, 2000)
1934	Tolerance dose: 0.17 R/day (measured in air) 0.2 R/day measured on surface of body	Fourth International Congress of Radiology[a] (Idaho State University, 2008)
		X-ray workers; for low LET, equivalent to 51 R/yr[a] or 510 mGy/yr (air) or 610 mGy (surface of body); ([a]*Note*: assuming 300 workdays/yr)
1946	Maximum permissible dose: 0.3 rem/wk	Informally set by NCRP[b]; Equivalent to 150 mSv/yr**;
1954	Max permissible dose: 0.3 rem/wk for critical organs; 0.6 rem/wk for skin	NCRP; no threshold; Equivalent to 150 mSv/yr** for critical organs; 300 mSv/yr** for skin (***Note*: assuming 50 workweeks/yr)
1955	Max permissible dose: Workers: 0.3 rem/wk for critical organs Public: 10 × lower than workers (or 0.03 rem/wk)	ICRP (2003); Equivalent to 150 mSv/yr**for workers; or 15 mSv/yr for the public *(Note: assuming 50 workweeks/yr)
1956	1.Except background radiation, (a) average accumulated dose to gonads not more than 10 rem/person up to 30 yr; (b)for individuals in general population, the dose should be limited to 50 rem up to 40 yr 2. occupational exposure limit = 5 rem/yr	ICRP 1. Equivalent to (a) 100 mSv/person up to 30 yrs;(b) 500 mSv up to 40 yrs. 2. Equivalent to 50 mSv/yr
1957	(a)Limit occupational exposure to 5 rem/yr (b)max permissible dose, 0.3 rem/wk for workers	(a) NCRP; 50 mSv/yr (b) US AEC[c] first set of regulations governing the use of radioactive material. Equivalent to 150 mSv/yr
1958	1. For occupational exposure: (a)no exposure below 18 yr (b)average of 5 rem/yr over their working life, limited exposure to less than or equal to 3 rem in any 13 consecutive weeks or 12 rem/yr for unusual events 2. For public exposure: Max whole body dose for public of 0.5 rem/yr, avg body burden not to exceed 1/10 that of radiation workers	NCRP 1 (b) equivalent of average of 50 mSv/yr over their working life; limited to30 mSv in any 13 consecutive weeks or 120 mSv/yr for unusual events 2. Equivalent to 5 mSv/yr max whole body for public exposure
1971	Limit to population: 0.17 rem/person/yr for whole body and gonad exposure; limits to fetal exposure to less than 0.5 rem (due to mother's occupational exposure)	NCRP Equivalent to 1.7 mSv/yr whole body and gonad exposure; fetal exposure less than 5 mSv/yr
1977	ALARA concept adopted; effective dose equivalent concept introduced; limit of 5 rem/yr for workers	ICRP (1977). Equivalent to 50 mSv/yr
1991	Occupational dose limit: 10 rem in five years(avg 2 rem/yr); Public dose limits: less than 0.1 rem/yr	ICRP (1991). Effective dose limit for workers: 20 mSv/yr averaged over 5 consecutive years; for public 1 mSv/yr for public;
2007	No changes in limits but terminology changed to dose constraints, range of effective doses: Workers: 1–20 mSv/yr; Public: < 1 mSv/yr	ICRP (2007) introduced protection of environment (no limits set yet) Dose constraints 20–100 mSv, ref level for radiological emergency; 1–20 mSv, ref level for occupational workers; < 1 mSv, ref level for public

Note: R/h ~rad/h for low LET radiation; 1 rad = 1 rem; 1 rem = 1 mSv; and 100 rad = 1 Gy.
[a] The International Congress of Radiology was the precursor of the International Commission for Radiological Protection (ICRP).
[b] NCRP refers to the US National Council on Radiation Protection and Measurements.
[c] US AEC is the former US Atomic Energy Commission (reorganized later into the US Nuclear Regulatory Commission and the Dept of Energy).

Criticisms on the LNT theory came soon after it was recommended in Brues (1958).

2. Debate on LNT

In the absence of any measurable scientific evidence of adverse health effects in man by low dose LET ionizing radiation, the LNT has served as a model that is considered conservative, prudent, and precautionary. It facilitates the administration of radiation protection programs. The thinking behind it is that if exposure to high doses of radiation demonstrates observable health risks to man, then there should also be health risks, albeit small or unobservable, at low doses of radiation, based on evidence of effects on organisms (e.g. cells, animals) other than man. For practical purposes however, there was a need to negate the zero-risk option and to set some finite levels of "acceptable risks" at any dose (Lindell et al., 2003).

In recent years the discussions on validity of LNT has intensified among professional societies and radiation protection community. (Mossman, 2008a; Leonard, 2008; Tubiana et al., 2007, 2008; Feinendegen et al, 2008; Maxley, 1997; Brenner et al., 2007.) Among the reasons cited are the following:

(1) *Lack of human data at low doses*. The statistically significant data are still derived from the atomic bomb survivor studies. This paper will deal more on this point.
(2) *Contradictory shape of the DR curve at low doses*. Studies or experiments to demonstrate the LNT at low doses result in contradictory shapes of the DR curve such as sigmoidal or showing bystander effects, threshold, or even hormesis. There have been arguments for and against each shape and the reader is referred to some references. (Breckow, 2006; Calabrese, 2003; Calabrese and Baldwin, 2001; Cohen, 1998; Higson, 2004; Mitchell, 2006; Oakley et al, 2005; Parsons, 2000, 2002).
(3) *Unwarranted creation of radiophobia*. The LNT creates in the minds of the public, fear of radiation, since it implies that any dose no matter how small, is not without risks. Never mind the fact that some population live in areas with naturally high background radiation than the recommended dose limits; or that thousands of pregnant women exposed to radiation from the Chernobyl fallout chose to abort pregnancy rather than give birth to what they erroneously believed would have been "mutant" or "defective" babies, etc.
(4) *Waste of economic resources*. The LNT-based standards are considered strict, and regulatory compliance to these standards