

## **Rulemaking1CEm Resource**

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Linear No-Threshold Model and Standards for Protection Against Radiation

**Comment On:** NRC-2015-0057-0086

Linear No-Threshold Model and Standards for Protection Against Radiation; Extension of Comment Period

**Document:** NRC-2015-0057-DRAFT-0547

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## General Comment

See attached file(s)

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## Attachments

LNT-comments(Hanekamp-Bast-Helsloot)

1 **The flawed logic of LNT - a short analysis**

2 **Docket ID NRC-2015-0057**

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21 **Introduction**

22 The U.S. Nuclear Regulatory Commission (NRC) has received three petitions for rulemaking (PRM) request-  
23 ing that the NRC amend its “Standards for Protection Against Radiation” regulations and change the basis of  
24 those regulations from the Linear No-Threshold (LNT) model of radiation protection to the radiation  
25 hormesis model. The radiation hormesis model provides that exposure of the human body to low levels of  
26 ionizing radiation is harmless and might even be beneficial by protecting the human body against deleteri-  
27 ous effects of high levels of radiation. Whereas, the LNT-model provides that radiation is always considered  
28 harmful, there is no safety threshold, and biological damage caused by ionizing radiation (essentially the  
29 cancer risk) is directly proportional to the amount of radiation exposure to the human body (response line-  
30 arity).

31 In this contribution we will focus on the legitimacy of the LNT-model of radiation protection. We will do  
32 that by examining the *validity* and *soundness* of the premises that characterise the LNT-model. Please re-  
33 member the bare essence of deductive reasoning. An argument is said to be *valid* if and only if it takes a  
34 form that makes it impossible for the premises to be true and the conclusion nevertheless to be false. Oth-  
35 erwise, a deductive argument is said to be invalid. A deductive argument is *sound* if and only if it is both val-  
36 id, and all of its premises are *actually true*. Otherwise, a deductive argument is unsound.

37 If the premises that lead to the validity and soundness of the core tenet of the LNT-model are shown to be  
38 defective in some way, then the LNT-model needs to be abandoned unequivocally. We are aware of the fact  
39 that that will have far-reaching consequences. Not only the discipline of radiology needs to incorporate that  
40 change, however defined, but also the ‘downstream users’ in multiple policy fields. With what the LNT-  
41 model needs to be replaced is another matter. However, what is clear is that any replacement needs to be  
42 empirically founded first and foremost, next to a valid and sound structure of the whole. Hormesis in our  
43 opinion seems to fit that bill. That we will however not investigate further here.

44 Our conclusion is that the LNT-model is unsound, and should therefore be abandoned both as a scientific as  
45 well as a regulatory construct.

46

47 **Analysis**

48 The classical stance on risk of radiation is: ‘Complexities notwithstanding, the genetic damage done, how-  
49 ever felt and however measured, is roughly proportional to the total mutation rate.’ ... ‘Any radiation is ge-  
50 netically undesirable, since any radiation induces harmful mutations. Further, all presently available scien-  
51 tific information leads to the conclusion that the genetic harm is proportional to the total dose .... This tells  
52 us that a radiation dose of 2X must be presumed to be twice as harmful as a radiation dose of X.’ [1]

53 Since the publication of ‘Genetic Effects of Atomic Radiation’ in 1956, any ionising radiation is regarded as  
54 ‘genetically undesirable’ (quite a partisan terminology we observe). Therefrom, the developed regulatory  
55 Linear No-Threshold (LNT)-model holds that for ionising radiation (*and* genotoxic carcinogenic chemical  
56 substances), *any level* of exposure –except for zero- implies a health risk. [2] Thus, only zero exposure is  
57 ultimately deemed to be ‘genetically’ safe.

58 This line of reasoning has been broadened to toxicology. Again, one ionising photon (or one molecule of a  
59 genotoxic carcinogen) may give rise to irreversible health damage: ‘Even at the lowest possible exposure  
60 (which, in theory, could involve just a single molecule), genotoxic carcinogens can still initiate the cancer  
61 process, although the risk is very small. This line of reasoning clearly indicates that when two molecules of  
62 carcinogen are present the risk involved is twice as great. In this way, a linear relationship could be created  
63 between exposure and the risk of a hit. This is also referred to as one-hit kinetics. It is based on the as-  
64 sumption that the probability of effective hits is directly proportional to the level of exposure’. [3]

65 Here, we want to raise an argument that fundamentally undermines the LNT-model as described above.  
66 This requires first, for sake of clarity, that the precepts of the LNT-model be rephrased into a logically valid  
67 argument of the following structure, *which simultaneously is regarded as sound*, considering the almost  
68 global acceptance of the LNT-model in research and policy:

- 69
- 70 (1) Ionising radiation causes genetic harm (mutations).
  - 71 (2) Genetic harm is by default detrimental to living organisms (including humans).
  - 72 (3) Genetic harm is proportional to the total dose of ionising radiation.
  - 73 (4) Thus, a radiation dose of  $2X$  is twice as harmful as a radiation dose of  $X$ .
  - 74 (5) The corollary of (4) (and (3)) is (assumed to be) that 2 photons of ionising radiation induce twice the amount of genetic  
75 harm compared to one photon of ionising radiation.
  - 76 (6) Consequently, even one photon of ionising radiation could create genetic harm, ultimately detrimental to the exposed or-  
77 ganism.

78

79 Premises (1) and (2) *prima facie seem* unproblematic; most accept both. However, premise (2) requires  
80 closer inspection. Our knowledge on the molecular mechanisms involved in the radiation induced DNA  
81 damage has increased tremendously during the last decades. Free radicals play an important role. At the  
82 start of this field of research (1970-1990), free radicals were regarded as the culprit. The reasoning was  
83 rather simplistic. Radiation splits the water molecule in which a very reactive hydroxyl radical is formed.  
84 These hydroxyl radicals damage DNA by oxidation.

85 Consequently, antioxidants, which prevent oxidation, should protect the DNA. Increasingly, it is realized  
86 that the mechanism is more complex. Some oxidation results in the activation of endogenous protecting

87 systems. Oxidation sensitive transcription factors (like Nrf2) have been discovered that activate the endog-  
88 enous antioxidants. Thus: damage induces protection. DNA repair systems are strongly regulated by mild  
89 damage. [4] So, premise (2) seems untenable, as damage, genetic harm, is not just a straightforward route  
90 towards disease but, conversely, initiates protection mechanisms bolstering genetic integrity. [5]

91 Furthermore, the soundness of premises (3) and (4) are by default limited to a range of dosages of ionising  
92 radiation that have actually been investigated either experimentally or epidemiologically. So, linearity of  
93 the dose-response curve is only known for a finite part of the whole of possible exposures levels, which is  
94 essential with respect to the lowest possible exposures up to the single photon or molecule.

95 The epistemological question therefore is whether premises (3) and (4) entail premise (5). Instead of the  
96 assumptive character implied in (5), one would need to *know* the empirical quality of premise (5) in order  
97 to conclude (6) and thereby implement LNT in radiation protection policy with all that that entails for so-  
98 ciety as a whole.

99 Premise (5) thus is the crucial assertion on which the entire LNT-model is built and does *not* seem to be  
100 acceptable. Proportionality of damage to dose, necessarily up to the single ionising photon, requires ex-  
101 traordinary empirical evidence in order to justify the soundness of this premise, and thereby the soundness  
102 of the whole argument.

103 So, the question is: In terms of research, what is required in order to show convincingly that premise (5) is  
104 sound? What kind of scientific experiment(s) would suffice to show that premise (5) is indeed tenable?  
105 Empirically, this seems impossible to do. No experiment would actually be possible to casually connect the  
106 perturbation of some part of the DNA by *one* ionising photon that subsequently would develop, over the  
107 organism's lifetime, into some disorder such as cancer. Worse, in view of the fact that damage induces pro-  
108 tection, premise (5) seems even less tenable. In conclusion, premise (5) is question begging. Premises (3)  
109 and (4) *do not* entail premise (5) whereby (6) altogether becomes moot.

110 Already in 1996, Goldman noted this palpable absurdity of the LNT-model when he linearly calculated the  
111 increased risk of cancer, due to increased cosmic radiation, if the entire world population would add a one-  
112 inch lift to their shoes (*sic*):

113 'As an extreme extrapolation, consider that everyone on Earth adds a 1-inch lift to their shoes for just 1  
114 year. The resultant very small increase in cosmic ray dose (it doubles for every 2000 m in altitude), mul-  
115 tiplied by the very large population of the Earth, would yield a collective dose large enough to kill about  
116 1500 people with cancer over the next 50 years. Of course no epidemiological confirmation of this in-  
117 crement could ever be made, and although the math is approximately correct, the underlying assump-  
118 tions should be questioned.' [6]

119

120 Goldman, despite his flippant exemplar, does describe the basic scientific and regulatory assumptions of the  
121 LNT-model correctly.

122 All in all, it seems clear that premise (5) is untenable, whereby the soundness of the entire argument for  
123 LNT is undercut, despite the fact that premises (3) and (4) might be correct within a limited exposure-  
124 range of ionising radiation. *That*, however, is irrelevant with respect to the extrapolative character of LNT  
125 towards diminishing levels of radiation exposures to which the public might be exposed.

126 Based on this concise analysis of the logic of LNT that has survived since the 1950s, it seems clear that LNT  
127 cannot be maintained empirically. Uncovering empirical evidence for premise (5) seems a hopeless cause.  
128 It is interesting to see that within the sciences a valid argument is implicitly and erroneously taken to be  
129 sound. That is a gross oversight that needs to be corrected.

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133 **References**

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