NRC Rejects Petitions to End Reliance on LNT Model

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Editor's note: *Newsline encourages perspectives on issues affecting the nuclear medicine community. This month we feature commentary on a longstanding effort to secure regulatory reassessment and invalidation of the linear-no-threshold (LNT) radiation model, which posits a linear relationship between dose and health risk and denies the existence of a threshold below which there is no harm, suggesting that radiation has the potential to cause harm at any dose level and that the sum of small exposures poses the same risk as a single larger exposure. Responses to this commentary are welcome.*

The Nuclear Regulatory Commission (NRC) on August 17 issued their rejection of three 6-year-old petitions requesting repudiation of the linear-no-threshold (LNT) model. The petitions maintained that the model is scientifically false and does more harm than good (*1*). The NRC contends that by overestimating radiation risk, adherence to the LNT model protects the public and radiation workers. The NRC relies on recommendations of authoritative scientific organizations that include the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation. It is our contention that unless NRC's policies comply with scientific evidence, they are as likely to *endanger* as to protect, and they directly contribute to avoidable early deaths.

Following ICRP and NCRP recommendations, the NRC concedes that no evidence supports the LNT model. Nevertheless, the NRC defends it, ignoring the fact that it was disproven at its 1940s birth in favor of a threshold model (*2*), as well as by data from the Life Span Study (LSS) of atomic bomb survivors (considered to be the gold standard for estimating radiation effects in humans) and the International Nuclear Workers Study (*3–5*). Even the most recent examination of the LSS data in 2017 by Grant et al. (*6*) concluded: "At this time, uncertainties in the shape of the dose response preclude definitive conclusions to confidently guide radiation protection policies." This stands in stark contrast to NCRP's 2018 Commentary 27, which wrongly asserted that Grant's study provided *strong* support for the LNT model.

Ever-expanding experimental and observational (epidemiologic) evidence demonstrates a threshold of radiation dose and/or dose rate below which harm disappears and the net effects on health, after the organism responds to protect itself, are beneficial (*3*). Such a threshold is common for many chemical and physical agents (e.g., oxygen, sunlight, water, vitamins, aspirin) and is called hormesis. The nonlinearity of net effect at low doses is a consequence of the biologic response of the exposed organism to the damage, a homeostatic defense mechanism, which is either repair of damaged DNA or removal of unrepaired cells through cell suicide and/or cleanup by the immune system.

The burden of proof should fall on the claim that radiation is an exception and causes harm even at low doses, which would imply that neither repair nor removal occurs. Although the evidence of benefit (which is forced to bear the burden in this argument) keeps multiplying as its mechanisms become further elucidated, the NRC and its advisers pretend otherwise. As the NRC notes, NCRP past-president John D. Boice, Jr., ScD, admitted that "the LNT model is not an appropriate mechanism to assess radiological risk," while at the same time advising that "[LNT is] a prudent basis for the practical purposes of radiological protection."

NRC indicates that NCRP Commentary 27 updated its assessment of currently available epidemiologic evidence and concluded that "the LNT model (with the steepness of the dose–response slope perhaps reduced by a DDREF [dose and dose rate effectiveness factor] should continue to be utilized for radiation protection purposes." DDREF has no physiologic basis, but its invocation indicates the realization that LNT is false. They refuse to admit that a dose (or dose-rate) threshold exists, but, in direct contradiction, state: "NCRP defines high dose rate as a dose rate above which recovery and repair processes are unable to ameliorate the radiation damage." The DDREF is an arbitrary mathematic construct that simply reduces the slope by a factor of 2 at doses $<$200 mSv, thereby artificially retaining linearity in this low-dose region while precluding hormesis by ruling out an initial *negative* slope.

Commentary 27 admitted that the LNT model's denial of a threshold "… likely cannot be scientifically validated by radiobiologic or epidemiologic evidence in the low-dose range" but claimed that "the preponderance of epidemiologic data is consistent with the LNT assumption, although there are a few notable exceptions." But a threshold has been found, repeatedly and for decades, from sources around the world (*4*). In short, the LNT model has been proven false in numerous studies (*3*,*7–9*), and hormesis has been proven to exist at low doses and dose rates (*3*).

The NRC, again following NCRP and ICRP, favors studies that *claim* to provide evidence for the LNT model. However, such studies employ circular reasoning, inaccurate dose estimates, violation of proper frequentist statistical procedures (including misassignment of the null hypothesis to represent the favored hypothesis [i.e., the LNT model],

making it more difficult to reject the model and wrongly interpreting failure to reject as equivalent to proof thereof), failure to seek confounders, and so on, all of which mask hormetic effects (*3*,*10*).

Grant et al. (*6*) unwittingly provided an illustrative example of misassignment of the null hypothesis in their recent reanalysis of the LSS data. They reported: "The evidence of a threshold dose below which there was no dose response was examined using linear-quadratic threshold models for males and linear threshold models for females. There was no [*sic*] evidence of a threshold for females (estimated threshold dose of 0.08 Gy). *This was not significantly different from 0* ($P = 0.18$), and the upper 95% confidence bound was 0.2 Gy. For males, the best estimate for a threshold dose was 0.75 Gy. Similarly, *this was not significantly different from 0* ($P = 0.49$)" [italics our emphasis]. Note that their implied null hypothesis, acceptance of a threshold at zero dose (equivalent to "no threshold"), is both illegitimate and completely arbitrary, since, from this approach, one could also validly choose a nonzero threshold anywhere between zero and the upper bound (i.e., anywhere between 0 and 750 mGy for males).

Tacitly admitting that the LNT model is unsupported by evidence, NCRP says "current judgment by national and international scientific committees is that no alternative dose response relationship appears more *pragmatic or prudent for radiation protection purposes* than the LNT model on the basis of available data, recognizing that the risk [for doses] <100 mGy [<10 rad] is uncertain but small" [our emphasis]. Despite the fact that the LSS data clearly exhibit an initial negative slope indicative of hormesis when the low-dose data are carefully examined (*8*,*11*), pragmatism and prudence are allowed to trump scientific validity.

Scientifically, NRC acts as though the evidence against the LNT model and in favor of hormesis is inconclusive. Pragmatically, despite the preponderance of evidence for hormesis, its policy appeals to the precautionary principle, which holds that when there is uncertainty (real or pretended), prudence demands erring on the side of caution. This might be justified if: (1) the promotion of the LNT model carried little to no harm; (2) its implied directive to use x-ray and CT doses as low as reasonably achievable (ALARA) were without negative consequences; and/or (3) it were acknowledged that a threshold actually exists and that hormesis should be universally recognized. None of these is the case. The ICRP LNT-derived principle of "optimization," generally practiced by radiologists, promotes the widespread misconception among physicians and the public that the LNT model accurately describes the effects of low-dose ionizing radiation (*5*). This misconception can inflict devastating harm on public health and safety.

One such harm has been radiophobia-driven forced evacuations, such as that in 2011 after the tsunami-caused Fukushima Daiichi nuclear event (*7*). This resulted in massive loss of homes, communities, jobs, property, and lives. The Japanese government admits to some 2,000 evacuation-caused deaths of elderly individuals who would have been far safer if allowed to shelter in place. The concomitant stresses have produced a sharp rise in heart attacks, strokes, alcoholism, divorces, joblessness, despair, and suicide.

LNT-derived radiophobia also induces many people to avoid medically indicated CT scans and other imaging, with consequent missed or delayed diagnoses and ineffective treatments (*5*). CT imaging with insufficient radiation produces similar outcomes. Alternative methods to CT and x-rays are widely encouraged, such as longer-duration MR studies requiring sedation for children or exploratory surgeries risking blood loss, infection, and, in some cases, death.

Misguided attempts to evade imaginary risks deprive adults and children of the far greater benefits of low-dose radiologic examinations, including accurate and timely diagnoses, effective therapies, lives saved, improved quality of life, avoidance of unnecessary surgeries, reduced hospital stays, and reduced costs, or, in the case of negative examinations, greater peace of mind.

Effective risk management and public communication regarding radiation incident-related evacuation policies and medical imaging are not possible until the LNT model and its corollary, ALARA, are universally acknowledged as scientifically and pragmatically indefensible. To properly manage and communicate risk at low radiation doses, the complete spectrum of possible health outcomes must be acknowledged (*7*).

The unintended side effects of a policy are as important as the intended direct effects. The need for a 2-sided assessment to replace simplistic 1-sided epidemiologic studies that misassign the role of the null to a then unrejectable hypothesis (*10*) remains unacknowledged by the NRC and its advisory organizations (and their overlapping memberships who generally reinforce the others' conclusions). In effect they comprise not several independent voices, but a single voice, diminishing the overall authority of their consensus (*12*).

Although the NRC's rejection of the petitions purports to address our criticisms, these criticisms are merely listed, followed by evidence-free "disagreements"—the very transgression of which the NRC wrongly accuses the petitioners. NRC simply declares that they bear no responsibility for resulting forced evacuations, imaging avoidance, or nondiagnostic CT scans. We let the reader judge such protestations of innocence.

It is long past time for the NRC and authoritative scientific organizations to forgo falsely presumed pragmatic prudence in favor of scientific accuracy. Erring in either direction from a scientifically valid policy inevitably endangers public health and safety, and recognition of this fact requires acknowledgment of the negative side effects of such deviation. Only then will the dangers be preventable.

REFERENCES

1. Nuclear Regulatory Commission. Linear no-threshold model and standards for protection against radiation. *Fed Reg.* 2021;86:45923–45936.

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