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Commentaries



Does the EPA Contradict Its Own Policies?

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The U.S. Environmental Protection Agency (EPA) is charged with the protection of the public from possibly harmful environmental contaminants. The EPA bases its risk assessments for population exposure to low-level ionizing radiation, as well as to other carcinogenic agents, on the linear no-threshold (LNT) hypothesis (Puskin 2009), which assumes that the risk of cancer due to a low-dose exposure is proportional to dose, with no threshold. Based on such a hypothesis, there is no safe level of radiation exposure or exposure to any other carcinogenic agent.

The LNT hypothesis, however, is contradicted by substantial data and is no longer supported by science-based evidence (Calabrese 2013, Cohen 2010, Cuttler 2010). Even EPA actions can be interpreted to contradict the LNT hypothesis. We note two examples of seeming inconsistency between EPA policy and EPA actions: (1) guidelines and recommendations put forth by the EPA concerning acceptable levels of radon gas in the home environment and (2) EPA testing that intentionally exposed human subjects to two environmental pollutants that are known carcinogens.

In the first example, we note that the LNT hypothesis implies that any radon exposure, no matter how small, is associated with a lung-cancer risk. By its support of the LNT hypothesis, the EPA accepts that the only safe level of radon gas is no radon gas. According to the information on the EPA web page (<u>epa.gov/radon</u>), the estimated risk of lung cancer for a nonsmoker exposed to radon gas levels of 0.15 Bq L⁻¹ is 0.7 percent using the LNT method—that is, 7 out of 1,000 nonsmokers are at risk for developing lung cancer from this exposure.

Nevertheless, EPA has set 0.15 Bq L⁻¹ as the action level above which EPA recommends that a homeowner take corrective measures and below which no action is needed. So most homeowners will not take any remedial action if their homes contain levels of radon gas at 0.15 Bq L⁻¹ and below. Thus the 0.15 Bq L⁻¹ action level represents a de facto "acceptable" level and a de facto threshold since most homeowners believe no action is required at or below the action level. This contradicts the EPA's endorsement of the LNT hypothesis.

Interestingly, the LNT hypothesis suggests that being exposed annually to 0.15 Bq L⁻¹ of radon gas presents the same lung-cancer risk as having 200 chest x rays per year. If the LNT model is correct,

how can there be a safe level of radon? Nevertheless, the EPA has set an acceptable threshold of 0.15 Bq L⁻¹, which seems to assert that 200 annual chest x rays represent an acceptable lung-cancer risk.

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It is important to point out that the risks calculated using the LNT hypothesis are only theoretical estimates that have never been observed and are solely based on extrapolation down to zero doses. Data have indicated that the LNT hypothesis may grossly overestimate cancer risks associated with radon inhalation (Cohen 1995).

The second inconsistency we note regards EPA's authorization under federal law to perform human testing so that it can regulate potentially harmful pollutants. A recent Inspector General (IG) report (2014) looked at studies conducted by the EPA in 2010 and 2011 that *intentionally* exposed 81 test subjects to concentrated airborne particles of diesel exhaust emissions, which are known carcinogens. The IG report notes that the consent forms used were inadequate since the exposure risks were not always consistently represented; for example, the forms did not discuss the potential cancer effects and even death that might result from these intentional exposures, assuming that the LNT hypothesis is correct. Six short-term adverse effects from these studies were noted by the IG report; the long-term toll of cancer deaths predicted by LNT was not addressed.

In its response to the IG report, the EPA stated that it considered the cancer risks from the studies to be *minimal* and noted that no one had died as a result of the testing (a questionable claim, since the tests were done only a few years prior and the expression of cancer and cancer-related death may take decades to occur). Yet, as with radiation, we would expect that if the EPA supports the LNT hypothesis, its studies would assume that *any* exposure to fine particles or diesel exhaust carries some nonzero risk of cancer induction. Furthermore, if these exposures follow the LNT rule, deliberately exposing human subjects to potentially harmful carcinogens seems contrary to EPA's own policy regarding LNT. Such low-level exposures are either safe or not, and the EPA's apparent contradiction in actions and policy is confounding.

The EPA has stated that "no level of radiation or environmental carcinogen is safe," yet EPA recommendations, guidelines, and human testing studies contradict this statement. If the LNT hypothesis is correct, is the public actually protected from harmful exposure to environmental contaminants when the EPA sets action levels or dose thresholds at nonzero dose values?

In our view, the logical solution to these contradictions is to accept that the LNT hypothesis is overly conservative and to cease promoting information that serves only to frighten the public, while providing no benefit to society and diverting monetary resources from activities that could be saving actual human lives. While it is certainly true that the LNT dose-response hypothesis is easy to understand and implement, we maintain that it places inappropriate emphasis on preventing completely theoretical cancer risks from exposure to low doses of radiation (Siegel and Stabin 2012).

References

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Response to Stabin and Siegel

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Alas, the dispute among health physicists over the linear no-threshold (LNT) hypothesis never ends!

Michael Stabin and Jeffry Siegel assert that LNT is contradicted by substantial data and is no longer supported by science-based evidence (Stabin and Siegel 2014). However, this view runs counter to the mainstream of expert scientific opinion on the risk of radiogenic cancer. For example, the National Academy of Sciences Biological Effects of Ionizing Radiation (BEIR) VII Committee stated that "the balance of evidence from epidemiological, animal and mechanistic studies tend to favor a simple proportionate relationship at low doses between radiation dose and cancer risk" (NAS 2006).

Likewise, based on an in-depth examination of current data on biological mechanisms at low doses, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reiterated its earlier conclusion that as far as is known, "even at low doses radiation may act as a mutational initiator of tumorigenesis and anti-tumorigenic defences are unlikely to show low-dose dependency. In general, tumorigenic response does not therefore appear to be a complex function of dose. The simplest representation is a linear relationship, which is consistent with most of the available mechanistic data" (UNSCEAR 2012).

Stabin and Siegel's rejection of LNT is indefensible when it comes to radon. Citing a 1995 paper by Bernard Cohen, they claim that LNT "may grossly overestimate cancer risks associated with radon [sic] inhalation." They appear to be unaware of the pooled analyses of residential case-control studies (Darby et al. 2005; WHO 2009), which directly show that LNT provides a reasonable estimate of risk at radon levels only slightly above the EPA action level. It should also be pointed out that EPA's action level was not chosen on a health-risk basis, but it was driven by the technical feasibility of achieving reliable and verifiable reductions by homeowners.

Otherwise, the points raised by Stabin and Siegel are mostly a matter of semantics. According to the dictionary, "safe" can mean "no risk" or "low risk." "Acceptable risk" can mean that the risk is so low

Those Linear No-Threshold Blues

Marvin Rosenstein Reprinted from "A Musing Columntune" February 1995 Health Physics Newsletter

Since the human data left us Without any low-dose facts We're lost on how to deal with The less than 10-rad whacks.

We've got those linear . . . those linear no-threshold blues.

The theories all have key flaws The experiments often vary The explanations are not solid And the science is quite hairy.

We've got those low-down linear . . . those low-down linear no-threshold blues.

Some people cry hormesis Some people yell repair Most people moan we don't know So let's pretend it's there.

We've got those very-low-down linear ... those very-low-down linear no-threshold blues.

Those low-down blues.

Health Physics Society

that it is of no concern, or it can mean that people accept a risk because of the perceived benefits, and it is difficult or impossible to reduce the risk further. In general, the meanings are clear from the context, but unquestionably the terms are sometimes used carelessly.

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The position of EPA remains that, in view of current scientific information, LNT is the most suitable basis for assessing radiation risks at low doses. But, as emphasized elsewhere, LNT implies that, at low doses, risks, while not zero, are low (Puskin 2009).

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