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OFFICE OF
AIR AND RADIATION

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemaking and Adjudications Staff

SUBJECT: Docket ID NRC-2015-0057

This letter transmits the comments of the U.S. Environmental Protection Agency on the petitions for rulemaking filed with the U.S. Nuclear Regulatory Commission concerning Linear No-Threshold Model and Standards for Protection against Radiation (PRM-20-28, PRM-20-29 and PRM-20-30). Thank you for the opportunity to review and comment on these petitions.

Sincerely,

Jonathan D. Edwards
Director
Radiation Protection Division

Enclosure

cc: Josie P. Piccone
Vince H. Holahan

U.S. Environmental Protection Agency's Comments on Linear No-Threshold Model and Standards for Protection against Radiation; Notice of Docketing and Request for Comment ID: NRC-215-0057-0010

The U.S. Environmental Protection Agency strongly disagrees with the petition to the Nuclear Regulatory Commission (NRC) to cease using the linear no-threshold (LNT) model as a basis for regulating exposures to ionizing radiation. The EPA's Carcinogen Assessment Guidelines [1] specify that LNT should be used as a default assumption unless there is compelling evidence that the biological mechanism for carcinogenesis is inconsistent with LNT. More specifically, the Guidelines state: "The linear approach is used when a view of the mode of action indicates a linear response, for example, when a conclusion is made that an agent directly causes alterations in DNA, a kind of interaction that not only theoretically requires one reaction but also is likely to be additive to ongoing, spontaneous gene mutation." Ionizing radiation clearly falls into this category.

Of all the agents demonstrated to be carcinogenic, the evidence for LNT is particularly strong for ionizing radiation. Within limitations imposed by statistical power, the available (and extensive) epidemiological data are broadly consistent with a linear dose-response for radiation cancer risk at moderate and low doses. Biophysical calculations and experiments demonstrate that a single track of ionizing radiation passing through a cell produces complex damage sites in DNA, unique to radiation, the repair of which is error-prone. Thus, no threshold for radiation-induced mutations is expected, and, indeed, none has been observed.

Over the last half century, numerous authoritative national and international bodies have convened committees of experts to examine the issue of LNT as a tool for radiation regulation and risk assessment. These include the U.S. National Academy of Sciences (NAS), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Ionizing Radiation (UNSCEAR). Again and again, these bodies have endorsed LNT as a reasonable approach to regulating exposures to low dose radiation. One exception was a French National Academy Report [2], which found low-dose radiobiological effects in vitro indicative of nonlinearity in the dose response. The most recent NAS report on the subject, BEIR VII [3], reviewed the available data and came to a very different conclusion. The BEIR VII study, which was sponsored by several federal agencies including the EPA and the NRC, determined that "the balance of evidence from epidemiologic, animal and mechanistic studies tend to favor a simple proportionate relationship at low doses between radiation dose and cancer risk." This is the position adopted by the EPA [4] after review by the Agency's Scientific Advisory Board, an independent group of distinguished outside scientists.

Since publication of BEIR VII, additional evidence has accumulated supporting the use of LNT to extrapolate risk estimates from high acute doses to lower doses and dose rates. In this connection, we would note, *inter alia,* results of epidemiological studies on: nuclear workers in the United States, France and the United Kingdom [5]; residents along the Techa River in Russia who were exposed to radionuclides from the Mayak Plutonium Production Plant [6,7]; and children who had received CT scans [8]. These studies have shown increased risks of leukemia and other cancers at doses and dose rates below those which LNT skeptics have maintained are harmless – or even beneficial.

Given the continuing wide consensus on the use of LNT for regulatory purposes as well as the increasing scientific confirmation of the LNT model, it would be unacceptable to the EPA to ignore the recommendations of the NAS and other authoritative sources on this issue. The EPA cannot endorse basing radiation protection on poorly supported and highly speculative proposals for dose thresholds or doubtful notions concerning protective effects from low-level ionizing radiation. Accordingly, we would urge the NRC to deny the petition.

References:

1. EPA. *Guidelines for Carcinogen Risk Assessment.* Risk Assessment Forum, EPA/630/P-03/001F, March, 2005.

2. Tubiana et al., *Dose-Effect Relationships and Estimation of the Carcinogenic Effects of Low Doses of Ionizing Radiation.* Academy of Medicine (Paris) and Academy of Science. Joint Report No. 2, 2005.

3. NAS (National Academy of Sciences). *Health Risks from Exposure to Low Levels of Ionizing Radiation. BEIR VII. Phase 2.* National Academy Press, 2006.

4. EPA. *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population.* Office of Radiation and Indoor Air, EPA 402-R-11-001, April, 2011.

5. Leuraud et al., Ionising radiation and risk of death from leukaemia and lymphoma in radiation-monitored workers (INWORKS): and international cohort study, *Lancet Haematol,* published online June 22, 2015 at: http://dx.doi.org/10.1016/S2352-3026(15)00094-0.

6. Krestinina et al., Leukemia incidence among people exposed to chronic radiation from the contaminated Techa River, 1953-2005. *Radiat Environ Biophys,* published online December 12, 2009: DOI 10.1007/s00411-009-0257-5.

7. Davis et al., Solid cancer incidence in the Techa River Incidence Cohort: 1956-2007, *Radiat Res* **184**, 56-65 (2015).

8. Pearce et al., Radiation exposure from CT scans in childhood and subsequent risk of leukemia and brain tumours: a retrospective cohort study, *Lancet,* published online June 7, 2012: DOI:10.1016/S0140-6736(12)60815-0.