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TITLE: Linear No-Threshold Model and Standards for Protection Against Radiation

COMMENT#: 555

From: Mary Beth Brangan [mailto:marybeth@eon3.net]

Sent: Thursday, November 19, 2015 11:49 PM

To: RulemakingComments Resource <RulemakingComments.Resource@nrc.gov>

Cc: Heddle James <jim@eon3.net>

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P.O. Box 1047, Bolinas, CA 94924

Contact: Mary Beth Brangan
Date: November 19, 2015
To Secretary
U.S. Nuclear Regulatory Commission Washington, D.C. 20555-0001
ATTN: Rulemaking and Adjudications Staff

SUBJECT: Docket ID NRC-2015-0057

These comments are in response to three petitions sent to the NRC in February 2015, NRC Docket number NRC-2015-0057. The petitions are closely related and ask the NRC to amend regulation 10 CFR 20, which limits how much ionizing radiation the general public can get, on top of background radiation (not including medical exposures) and for how much exposure to workers at NRC regulated facilities.

The petitions for rulemaking were filed by D. Carol Marcus (PRM-28), Mr. Mark Miller (PRM-29), and Dr. Mohan Doss (PRM-30). On the Web at <http://www.regulations.gov/#!documentDetail;D=NRC-2015-0057-0010>

EON 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 evidence, based on mega-studies, both recent and past all point to the fact that no dose of radiation is without risk; that doses are cumulative and additive and that current allowable levels are already too high.

In fact, the levels of exposure from years of uranium mining, weapons manufacturing, and nuclear power reactor routine emissions and disasters have raised the natural background radiation with now ubiquitous man-made radiation. The levels of beta and gamma radiation shown by the EPA's Radnet have been showing high readings in many cities. Fukushima fallout has been detected in many cities water and milk. Fukushima fallout continues unabated both into the air and into the Pacific oce.

It appears that these three individual petitioners propose to deal with this ongoing buildup of radioactivity and the prospect of more statistically inevitable major accidents and severe weather caused releases of radioactivity by merely having the NRC wave a wand to deny years of accumulated data by the most eminent global scientists that show increased levels of risk of biological damage at even lower levels that were formerly thought possible.

The proposals for allowing more radiation exposure to the general public would benefit only corporate profits because they alleviate the responsibility for nuclear industry clean up and safety measures. It would also deny assistance to those who need to be evacuated when these inevitable accidents occur.

There is no empirical evidence for a "safe" dose of radiation and growing evidence to support the finding that any exposure to ionizing radiation carries risk of harm.

US radiation regulation of exposure to ionizing radiation is based on the linear-no-threshold (LNT) model for risk of cancer which assumes a constant rate of risk per unit of radiation exposure. More radiation is more risk, but every level of exposure above zero has some risk.

As you no doubt know, there are two very large data-sets, the Japanese Hibakusha, A-Bomb survivors (~90,000) and an international group of atomic workers (~250,000), both tracked for decades from which many papers have been published. The size of these data-sets allow statistical models to be applied and compared. The findings are narrow, due to limitations in both studies, but the large size of the study populations improves that “signal to noise” ratio and findings made by qualified researchers show that the LNT model fits the real-world data better than a “safe threshold” model.

The National Academy of Sciences Biological Effects of Ionizing Radiation VII Phase 2 Report or BEIR VII (2006,) is the most comprehensive publication of the A-Bomb Survivor Life Span Study data and findings. The authors of BEIR VII state:

The committee judged that the linear no-threshold model (LNT) provided the most reasonable description of the relation between low-dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation. (Introduction p 5 of BEIR VII)

A team of researchers led by Richardson of UNC Chapel Hill published findings in BMJ on the international workers data-set in October of 2015. The research question addressed in the paper is:

Is protracted exposure to low doses of ionizing radiation associated with an increased risk of solid cancer?

The discussion of Findings states:

This study provides evidence of a linear increase in the excess relative rate of cancer mortality with increasing exposure to ionising radiation at the low dose rates typically encountered in the nuclear industries in France, the UK, and the USA.

There is no level of radiation exposure that produces direct health benefit, and sufficient evidence to end any debate and declare it a fact: radiation exposure never directly improves health. Claims of Hormesis are false.

In 2012 Moeller and Mousseau published “The effects of natural variation in background radioactivity on humans, animals and other organisms” a meta-analysis of 46 papers in the literature, collectively reporting 373 different findings of impact from radiation exposure. The paper looked solely at exposure from background radiation away from industrially contaminated zones.

From the Discussion section of the paper (page 24—25):

Hormesis is defined as a beneficial effect of normal background radiation on life-history traits such as fecundity and longevity compared to levels achieved in the complete absence of radiation (reviews in Kondo, 1993; Luckey, 1991). If hormetic effects of radiation on fitness exist, we should expect that the optimal level of radiation should increase with background radiation level. If hormesis has evolved as a consequence of local adaptation to specific levels of radiation, we might even find that all populations should perform best at some local level of radiation; exceeding their performance in the absence of radiation. The latter scenario would suggest that fitness should be independent of level of natural background radiation. In either case, we should not expect to find increased mutation rates, impaired immune function, increased incidence of disease and increased mortality in areas with higher levels of normal background radiation. Our findings are clearly inconsistent with a general role for hormesis in adaptation to elevated levels of natural background radiation. We note that some effect sizes reported herein were negative, thereby deviating from this expectation. However, these effects were of a level that would be expected by chance, inconsistent with expectations for a hormesis hypothesis.

This is empirical evidence-based conclusions. The authors of the Petitions do not offer similar data to support the assertion that Hormesis exists.

The US EPA concludes its comment on the current proposal:

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.

Because of the increased risk to the unborn, children, women and elders, Petitioners are effectively declaring a policy of reduced years and quality of life

The Petitioners ask NRC to “End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.” In apparent indifference, or ignorance of the findings by Makhijani (2006) and Olson (2011) that ionizing radiation impacts females to a greater degree than males, and that this impact is greatest in young children. Similarly, the work of Alice Stewart (1958) has documented with strong statistical significance that when pregnant women are X-rayed there is a doubling (or more) of childhood cancer in those that were irradiated in utero. It was Dr. Stewart who also documented an upward tick in the risk of cancer from exposures late in life. Dr. John Gofman warned of the dangers of increased risk from medical use of radioactivity.

Dr Ian Fairlie has recently provided an assessment of German nuclear reactor radioactive release data obtained by the International Physicians for the Prevention of Nuclear War showing with high certainty that airborne releases of radioactivity during refueling account for childhood leukemia clusters previously documented near reactors in that region. This is additional, new empirical data that the human lifecycle is vulnerable to the impact of ionizing radiation exposure and must be protected.

Choosing unlimited exposure to radiation below the level that these nuclear advocates deem to be harmful (10 rems) could, in a short period of time render “normal” DNA obsolete.

For all of these reasons I urge the NRC Staff to reject these petitions.

Thank you for this opportunity to comment,

Mary Beth Brangan
Co-Director

Richardson, et al, October 2015. BMJ. <http://www.bmj.com/content/351/bmj.h5359>

Moeller and Mousseau, 2012.

http://www.researchgate.net/publication/233382836_The_effects_of_natural_variation_in_background_radioactivity_on_humans_animals_and_other_organisms

NAS 2006, BEIR VII (entire free download) Summary: http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/beir_vii_final.pdf and Full:

<http://www.cirms.org/pdf/NAS%20BEIR%20VII%20Low%20Dose%20Exposure%20-%202006.pdf>

Olson, Atomic Radiation is More Harmful to Women:

<http://www.nirs.org/radiation/radhealth/radiationwomen.pdf>

And Arjun Makhijani / IEER Healthy From the Start Campaign on radiation and girls:

<http://ieer.org/projects/healthy-from-the-start/>

Stewart, et al, 1958. "Survey of Childhood Malignancies" British Medical Journal, June 28, pages 5086 – 1508.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2029590/>

Ian Fairlie slides: download page here: <http://www.nirs.org/radiation/radhealth/ianfairlieepalecture415.ppt>

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT - 7 2015

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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

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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: C-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 [I] 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 US Population*. Office of Radiation and Indoor Air, EPA 402-R-11-001, April, 2011.
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