February 24, 2015

Annette L. Vietti-Cook
Secretary, USNRC
Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852.

Dear Ms. Vietti-Cook:

We are submitting this petition for rulemaking pursuant to 10 CFR Part 2.802. The petitioners request that the NRC amend 10 CFR Part 20, Standards for Protection Against Radiation, based on science and evidence that contradicts the Linear No-Threshold (LNT) hypothesis, a model that has served as the basis for radiation protection regulations since the 1950s. This petition supports and supplements the recent petition dated Feb 9, 2015, submitted by Dr. Carol S. Marcus, a copy of which is enclosed for completeness and ease of reference.

The LNT model claims an excess risk of cancers from even the smallest amount of radiation exposure due to DNA damage. Though, on the face of it, the model seems logical, it is not correct because it ignores the fact that our bodies have very powerful defenses against all damages that occur. In fact, there is considerable naturally-occurring DNA damage in our bodies even without any radiation exposure. Although a small amount of radiation produces a small amount of damage, it stimulates the activities of our defenses, including production of antioxidants, DNA repair, damage removal, and improved immune responses (1). As a result, there would be less naturally-occurring damage, and therefore fewer diseases including fewer cancers.

Whereas many publications have claimed support for the LNT model or for low-dose radiation (LDR) cancer risk, careful scrutiny has shown these claims to be without merit, as major deficiencies have been identified in their study design, data, analysis, and/or interpretation. For example, two recent studies claimed increased cancers following childhood CT scans (2, 3), and these publications have been frequently cited in both public and professional media, raising fear of childhood CT scans. However, deficiencies identified in these publications make them not credible (4-7). The 15-country study of radiation workers (8), cited in the BEIR VII report (9) as supplementary evidence for LDR cancer concerns, no longer supports such concerns because the Canadian data in that report were assessed to be incorrect and have been withdrawn from use by Health Canada (10, 11). By referring exclusively to such faulty publications and ignoring publications which present evidence against the LNT model (without explaining why those publications were ignored), advisory bodies and regulatory agencies are able to maintain the appearance of adhering to the scientific method in their continuing support for the LNT model. This strategy was in full display at the recent BEIR VIII Scoping Meeting at the National Academy of Sciences where the faulty pieces of evidence cited above were discussed by speakers (12) while other evidences against the LNT model (mentioned in the petition by Dr. Marcus and in the discussion below) were ignored and not mentioned.

The primary data generally used for estimating the health effects of LDR are the atomic bomb survivor data as stated in the BEIR VII report (9) and in other publications (13). The conclusion of the BEIR VII report was that the data are consistent with the LNT model. However, the latest update to the atomic bomb survivor cancer mortality data by Ozasa et al., published in 2012, is no longer consistent with the LNT model, since the dose-response data have a significant curvature or deviation from linearity in the 0-2 Gy dose range, resulting from the lower than expected cancer rates in the 0.3-0.7 Gy region (14). Ozasa et al. had no explanation for the observed reduction of cancers in this dose range. When a correction was applied for a likely negative bias in the baseline cancer mortality rate (based on radiation hormesis occurring in the lowest dose cohorts), the corrected dose response was shown to attain a shape consistent with radiation hormesis (15, 16). Thus, the radiation hormesis hypothesis (i.e., a favorable biological response to low doses of ionizing radiation) can provide a possible explanation for the shape of the dose-response data, whereas there is no explanation using the LNT model.

Though Ozasa et al. performed a dose-threshold analysis and concluded that zero dose is the best estimate of the threshold dose, their dose-threshold analysis was flawed, since it used a restricted functional form for dose response that did not cover the full range of the observed data. Analysis with a more general functional form has shown that a non-zero dose threshold cannot be excluded (16, 17). Thus, the atomic bomb survivor data do not lead to the conclusion of zero dose threshold, contrary to the claim by Ozasa et al.

In view of the above analysis, the use of the LNT model is no longer justifiable, since the atomic bomb survivor data, which are recognized as the most important data for estimating the health effects of LDR, do not support the LNT model. This has been recognized in the latest published debate on the health effects of LDR (18), where the atomic bomb survivor data were not quoted to support LDR carcinogenic concerns in the opening statement, in contrast to earlier such debates (19).

There are additional data (supplementing those presented in the petition by Dr. Marcus) that support the concept that low-dose radiation reduces cancer risk. These include: (i) The nuclear shipyard worker study in which radiation workers with radiation dose of ~4 cGy had significantly lower cancer mortality rates in comparison to workers from the same shipyard who received no occupational radiation dose (20), (ii) A study of childhood cancer survivors who had undergone radiation therapy showed reduced second cancers per kg of tissue in regions of the body that had received radiation dose of ~20 cGy in comparison to regions of body that had received no radiation dose from the radiation treatments (21), (iii) Clinical trials of low-dose radiation treatment given to the whole body repeatedly over a five week period showed a cancer therapeutic effect from the LDR treatments with similar or better patient survival compared to chemotherapy, and with no observable side effects (22-24), and (iv) A clinical trial of low-dose radiation treatment administered to the whole body or half body between standard radiotherapy of the tumor showed improved patient survival (25).

Many ecological studies have also shown reduction of cancers with increased background radiation. Though ecological studies have been challenged (e.g. by BEIR V and BEIR VII reports) with the claim that they are subject to ecological fallacy, important discoveries have indeed been made from such studies (26), and so ecological studies should not be dismissed without due consideration. A study of cancer mortality rates in the states of the USA as a function of mean background radiation dose rates showed reduced cancer mortality rates for the states with the highest background radiation dose rates (27). Comparison of residential radon levels and lung cancer rates in the counties of the USA has shown an inverse correlation between radon levels and lung cancer rates (28). A comparison of maps of radon levels and lung cancer rates has shown repeatedly that the areas with the highest radon levels generally have lower levels of lung cancer, and the areas having the highest rates of lung cancer generally have lower radon levels (29). The repeated observation of this pattern in different countries and states, states with low smoking prevalence, states with high smoking prevalence, states with lower mean radon levels, states with higher mean radon levels, etc., and the consistency of the observation with other evidence for the cancer preventive effect of LDR indicate the observation of reduced lung cancers with increased radon levels is likely to be a causal effect rather than due to confounding by other factors. In view of this, supplementation of radon levels in residences having low radon levels would likely result in reducing lung cancer rates. However, clinical trials to test this concept would not be feasible with the current NRC regulations based on the LNT model. Since lung cancer is one of the most deadly cancers and the leading cause of cancer death in the USA, the current LNT model-based regulations, by discouraging and preventing such clinical trials, have likely had a major detrimental effect on public health. The LNT-model-based radon remediation program, recommended by government agencies such as EPA, is likely leading to increased lung cancer risk in the population, based on the observations in these ecological studies.

The use of the LNT model-based regulations over the years has resulted in a tremendous increase in the staffing of the regulatory agencies and a huge financial benefit for industries and personnel that support compliance with the regulations. The regulations have, however, had a major detrimental effect on public health, since they have prevented the study of LDR for controlling aging-related diseases such as cancer, Alzheimer's disease, Parkinson's disease, etc. in spite of studies showing the promise of LDR for the diseases (30, 31).

Considering that the LNT model originated in the 1950s due to the self-interest motivation of members of advisory bodies (32), as mentioned in the petition by Dr. Marcus, similar motivation cannot be ruled out for its continuing support by later advisory bodies, since they have failed to respond to accumulating evidence against the LNT model and have continued to support the use of the LNT model. Regulatory agencies such as EPA and NRC also have a self-interest motivation for the continued use of the LNT model, since the model justifies the current regulations relating to low radiation doses, and the use of a threshold model would reduce and eliminate these regulations, resulting in a tremendous downsizing of the regulatory agencies and their scope. Hence, petitions which ask for the discontinuation of the use of the LNT model should not be dealt with by NRC directly, but by an independent committee set up external to the NRC, in order to avoid major conflict of interest issues.

One reason for the urgency of action on this petition is that any potential future accident involving release of radioactive materials in the USA would likely result in panic evacuation because of the LNT- model-based cancer fears and concerns, resulting in considerable casualties and economic damage such as have occurred in Fukushima. The recognition of a threshold dose by NRC would obviate the need for such panic evacuations, associated casualties, and economic harm.

Whereas the government (through the regulatory agencies) has looked to advisory bodies for guidance on LDR health effects in the past, considering the self-interest motivation of the advisory bodies in the origin of the LNT model and its persistence, it would be advisable for the government to conduct its own evaluation of the evidence in order to set its policies rather than relying on the recommendations of the present advisory bodies or the present regulatory agencies, because of the major conflict of interest issues. This evaluation should be done by a committee independent of the current regulatory agencies.

Since the main body of evidence that has been used to justify LDR cancer concerns and the LNT model, the atomic bomb survivor data, does not support the LNT model but is more consistent with radiation hormesis, and in view of the large body of unrefuted evidence for radiation hormesis, the LNT model-based regulations have likely caused a large number of preventable cancer deaths over the years, by prohibiting the study and application of radiation hormesis to prevent cancers. The large magnitude of these preventable deaths would justify a

Congressional inquiry to determine why the scientific leaderships of the regulatory agencies and advisory bodies have failed to recognize the published evidence against the LNT model and supporting radiation hormesis for such a long period of time, and what role self-interest may have played in motivating these actions by the agencies and advisory bodies.

In conclusion, we support the changes recommended in the petition by Dr. Marcus. Obviously there will have to be many other major changes to NRC regulations (in addition to those listed in the petition by Dr. Marcus) when 10 CFR Part 20 is brought up to present scientific standards. But it all needs to start with ending reliance on the LNT model.

Thank you for your attention and consideration.

Sincerely,

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Note: All signers of this petition are members or associate members of SARI (Scientists for Accurate Radiation Information, http://radiationeffects.org/). The above letter represents the professional opinions of the signers, and does not necessarily represent the views of their affiliated institutions.

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