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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:

I am submitting this petition for rulemaking pursuant to 10 CFR Part 2.802. The petitioner requests that the NRC amend 10 CFR Part 20, *Standards for Protection Against Radiation*, based on new science and evidence that contradicts the Linear No-Threshold (LNT) hypothesis, a model that has served as the basis for radiation protection regulations. I will present scientific data as reported in study after study to justify that safety regulations and policies should no longer be based on the scientifically unjustified LNT model. This overly-simplified concept assumes that all radiation absorbed doses, no matter how small, have a finite probability of causing a fatal cancer. This is demonstrably false, as evidenced by over 60 years of operational dose data, countless peer-reviewed studies and the practices of radiation oncology and radionuclide therapy. Use of the LNT assumption encourages regulators to ratchet down permissible worker and public radiation levels, either through actual dose limits or use of the “as low as reasonably achievable” (ALARA) principle, giving the illusion that they are making everyone safer. Ironically, it is the erroneous use of LNT and its use to justify ALARA that has led to persistent radiophobia that we see everywhere today. There has never been scientifically valid support for this LNT hypothesis since its use was recommended by the U.S. National Academy of Sciences Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel in 1956. The costs of complying with these LNT-based regulations are incalculable. Dr. Gunnar Walinder has summed it up: “The LNT is the greatest scientific scandal of the 20th century (1).”

On the contrary, there are numerous experiments which document no effects and even protective effects at relatively low-dose and low-dose-rate radiation exposures. The literature showing no effects supports a threshold concept, in which radiation below a certain level is of no concern because it causes no deleterious effects. The literature showing protective effects supports the concept of hormesis, in which low levels of potentially stressful agents, such as toxins, other chemicals, ionizing radiation, etc., protect against the deleterious effects that high levels of these stressors produce and result in beneficial effects (e.g. lower cancer rates). To properly characterize risk at low radiation doses, a range of health outcomes, including beneficial or zero health effects, must be acknowledged.

Biological organisms are exceedingly complex, and have evolved in a world full of stressors, particularly oxygen, and also the bombardment by low dose background radiation from above, below, and within our own bodies. More than 150 genes have been recognized so far that are involved in defense of the organism and the production of defensive systems to protect against noxious agents. Although low-level radiation absorbed dose may cause cellular damage (including single- and double-strand breaks in DNA), this radiation also up-regulates a system of protective mechanisms in cells, tissues, animals, and humans that counteract the damage and then protect far more than they were damaged in the first place. It turns out that counting single- and double-strand breaks is a good measure of radiation dose, but is completely meaningless in estimating risk from low-dose radiation. As the levels of radiation absorbed dose rise, the damage and benefits equalize, and at higher doses the overall effect is harm, which is widely understood and acknowledged (2).

The fortunes of the United States have been founded upon advances in science and technology. Americans in general have embraced progress. Why then do regulators adhere to the LNT model to put a choke hold on radiation-related activities? Why is valid science being denied, while the invalidated LNT ideology based on erroneous evidence continues to be embraced? It is important to answer this question to fully understand how such a myth perpetrated on society could have survived for so long.

Regulators use the LNT assumption because nationally and internationally respected bodies recommend and advocate it. NCRP, ICRP, IAEA, and NAS-NRC's BEIR Committee care some of them. However, it seems that they are willing to abandon their scientific principles to maintain the *status quo*. It is going to take a good deal of courage to stand up and state that "The Emperor has no clothes." However, it is inevitable.

In 2001 the NCRP published Report No. 136 entitled "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation" (3), in which the LNT was upheld. In 2003 Zbigniew Jaworowski of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and Michael Waligorski destroyed that Report with an astonishing exposé of scientific misconduct (4). Every radiation regulator should read this scathing indictment of the NCRP Report. It is not highly technical, and requires no advanced mathematical ability.

Prof. Edward J. Calabrese of the Univ. of Massachusetts has traced amazing scientific misconduct by the nation's leading geneticists in mid-twentieth century (5, 6, 7). He states, "This paper extends a series of historical papers which demonstrated that the linear-no-threshold model for cancer risk assessment was founded on ideological-based scientific deceptions by key radiation genetics leaders. Based on an assessment of recently uncovered personal correspondence, it is shown that some members of the United States (US) National Academy of Sciences (NAS) Biological Effects of Atomic Radiation I (BEAR I) Genetics Panel were motivated by self-interest to exaggerate risks to promote their science and personal/professional agenda. Such activities have profound implications for public policy and may have had a significant impact on the adoption of the LNT model for cancer risk assessment." It should be acknowledged, at that point in history, there was no scientific data available to definitively conclude whether or not radiation caused radiation damage. Therefore, it might be

understandable that genetic risk was a reasonable concern and a precautionary approach, combined with Cold War concerns, provided the pressure to adopt a simplified LNT approach that might have been reasonable at the time. However, since then, scientific studies have conclusively shown that radiation does not cause genetic damage that affects future generations. Nevertheless, the antinuclear movement of the Cold War era continued to promote the scientifically unfounded myth that harm at any level of radiation would occur as part of their antinuclear-everything agenda.

There are countless peer-reviewed scientific papers that show that the LNT model is in error. There are several textbooks in this field, and journals that publish scientific findings that refute the LNT model. This is an entire field of science that regulators apparently pretend does not exist. Its continued existence certainly doesn't reflect the tenants of the scientific method. Imposing it upon the citizens of the United States (and the world, since others look to the practices observed in the USA) must stop.

There are numerous human situations in which we have good data that support radiation hormesis. Sadly, there are scientists who look at these data and ignore the apparent beneficial effect of low doses of radiation. When they make graphs of relative cancer risk vs. radiation absorbed dose, they simply draw a straight line **that misses the low dose points** and then proclaim that their data support the LNT model. The most commonly referenced study is the Life Span Study of the Radiation Effects Research Foundation (RERF) which studies the **Japanese atomic bomb survivors**. Recent data (8) show a hormetic effect for all solid cancers in the 0.3-0.7 Gy (30-70 rad) dose range, and the study of leukemia rates in the 96,000 survivors (9) showed hormesis at low doses, with a threshold at about 500 mSv (50 rem).

Workers exposed in the **nuclear power industry** comprise the largest group of occupationally exposed workers studied. They generally receive low radiation doses. Over 400,000 workers were studied from 154 facilities in 15 countries (10, 11) and the study showed a decrease in the risk of all cancers including leukemia. The BEIR VII report from the National Academy of Sciences points out that in most of the nuclear industry worker studies, mortality from all cancer and all causes is substantially lower than the reference population. While they have no explanation for this phenomenon, which could be caused by radiation hormesis, the National Academy Committee suggested the possibility of a "healthy worker effect". This mysterious effect is often cited to explain lower cancer rates in workers receiving low doses of radiation, but a little thought will show that the "healthy worker effect" is not supported by the data, while hormesis is a perfectly good alternative explanation.

Thirty-one thousand, seven hundred and ten female patients with tuberculosis in Canadian sanatoriums from 1930-1952 were subjected to multiple fluoroscopies to monitor their disease status. Of these patients, 26.4 % received radiation doses to the affected side of 10 cGy (10 rads) or more, and therefore most received lower doses. The relative risk of eventual breast cancer was studied in all these patients. **Patients who received a total radiation absorbed dose in the range from 5 – 30 cGy (5-30 rads) had a breast cancer incidence up to one third less than the background incidence.** Only at radiation absorbed doses above 50 cGy (50 rads) did the cancer incidence begin to increase above baseline (14, 15).

The radium dial watch painters comprise another group of radiation exposed workers. In some 900 young women who sharpened paint brushes with their tongues, there were 54 bone sarcomas and 25 carcinomas of the mastoids and paranasal sinuses. Radium is a bone seeker. **None of these malignancies occurred at a radiation absorbed dose to bone less than 10 Gy (1000 rads) (16).** While these studies were not designed to demonstrate hormesis, they do show a threshold, and a very high one, for the induction of bone cancer.

Following World War II, after the construction of nuclear reactors and the expansion of peaceful uses of atomic energy, patients with hyperthyroidism were treated with radioactive iodine-131 (I-131); this is still the treatment of choice today. While the I-131 cured the hyperthyroidism, there was a concern about late effects from the radiation. The Cooperative Thyrotoxicosis Therapy Follow-Up Study of over 36,000 treated hyperthyroid patients looked at eventual leukemia rates in these patients, as leukemia is considered the most radiosensitive of cancers and occurs faster than other radiogenic cancers. The total body radiation doses to these patients were 130-140 mSv (13-14 rem). **The age-adjusted leukemia incidence rate was 11/100,000 patient years in the I-131 treated patients and 14/100,000 patient years in patients treated by surgical removal of the thyroid gland (the standard procedure before I-131 became the therapy of choice).** While the authors concluded that there was no increased incidence of leukemia at this low whole body radiation dose (17), **the 22% decrease in the I-131 treated patients suggests a possible hormetic effect.**

The explosion of radioactive waste from a nuclear fuel reprocessing facility called “Mayak” in 1957 resulted in a stream of radioactive waste affecting an area in the East Urals of Russia. Research was performed on data collected from 1957-1987 on occupants of the 22 villages evacuated from the radioactive waste zone (18). Radiation absorbed dose groups were made for those receiving 40 mSv (4 rem), 120 mSv (12 rem), and 500mSv (50 rem). **Although all three groups had less cancer than the baseline expected in the area, the 50 rem and 12 rem groups were statistically significantly lower than the baseline cancer rate expected, suggesting hormesis.** The cancer death rate in the 50 rem group was 29% lower than the controls, and in the 12 rem group was 39% lower than the controls.

In 1982, several orphan cobalt-60 (Co-60) sources were recycled accidentally in the steel scrap industry in northern Taiwan. This resulted in the Co-60 contamination of more than 20,000 tons of steel used in the construction of over 200 residential, industrial and school buildings in Taiwan. In 1992, this contamination was identified and the exposed population was studied for cancer incidence (19). The population of 7271 people representing 101,560 person-years at risk was exposed to chronic radiation amounting to an average of about 5 cGy (5 rads) from 1983-2002. The range of radiation exposure was <1-2363 mSv (<0.1-236 rem). **The standardized incidence ratios (SIR) and the 95% confidence intervals calculated for all cancers was 0.8 (0.7, 1.0), for all cancers except leukemia was 0.8 (0.6, 0.9), and for solid cancers was 0.7 (0.6, 0.9).** (A SIR of 1.0 means the same as that of unirradiated controls.) The lowered cancer incidence rate was significant at the 95% confidence interval for all cancers except leukemia and for solid cancers. The lowered cancer incidence rate for all cancers was significant at the 90% confidence interval. The lowered cancer incidence rates in these people exposed to chronic, low levels of radiation suggest radiation hormesis.

The situation with residential radon exposure and lung cancer is most interesting. The seminal research of Bernard Cohen (20, 21, 22, 23) in the United States showed that **increasing levels of residential radon were associated with decreasing levels of lung cancer**. His data were carefully corrected for 54 socioeconomic variables, including smoking, but the inverse correlation of radon levels with lung cancer did not change. Dr. Bobby Scott (24) has analyzed the situation and has shown that low-level radon and its radioactive daughters cause activated natural protection against lung cancer, including smoking-related lung cancer, at levels up to the Environmental Protection Agency's (EPA's) action level of 4 picocuries/L (about 150 Bq m⁻³). Somewhat above this level, the activated natural protection effect progressively goes to zero and it is here that we see an increase in lung cancer. From this, we must conclude that **low levels of radon are hormetic**. Klaus Becker (25) has shown similar correlations in data from Central Europe.

In 1986, the Chernobyl reactor accident riveted much of the world, prompting huge hysteria (26). In the former Soviet Union, 336,000 people were forcibly evacuated, some from areas with five times lower radiation levels than are present in Grand Central Station in New York City, which is constructed with natural granite. There were large numbers of unnecessary abortions in Western Europe due to fears of mutant babies. Huge amounts of food were wasted because of miniscule levels of contamination which would hurt no one. The LNT was responsible for much of the hysteria, multiplying very small radiation doses times hundreds of millions of people to estimate huge numbers of cancer deaths. The affected population in the former Soviet Union was followed for increased cancer incidence. According to UNSCEAR 2000b (27) and the United Nations Chernobyl Forum in 2006, except for thyroid cancers in the highly contaminated areas, there was no increased incidence of leukemias or solid tumors, and no evidence of increased genetic diseases. The increase in thyroid cancers was found in children under 15 years of age in 1987, the year after the accident. However, the radiation doses were too low to have caused this, and there was no dose-response relationship. In addition, the timing was off---the mean latent period for radiation-induced thyroid cancer is about 28 years (27). However, the increase was highly likely due to a mass screening effect (22). Occult thyroid cancer is actually extremely common, with an autopsy prevalence in various countries of 4.5% to 36% (28, 29). These are small cancers that never caused problems and were unknown during the person's lifetime. The development of sensitive ultrasound techniques have made the diagnosis of these occult cancers, or "incidentalomas", much more common. In the United States, a screening program uncovered a 2100% increase in thyroid nodules (30), and mandatory yearly screening in children in the contaminated areas around Chernobyl resulted in a similar phenomenon. **According to Jaworowski (26), the natural incidence of occult thyroid cancers is approximately 1000 times higher than the highest incidence of reported thyroid cancers in the countries with the greatest fallout from the Chernobyl accident. The supposed increased finding of thyroid cancer due to radiation from the Chernobyl accident is instead due to intense screening (31).** The Chernobyl accident resulted in 28 radiation deaths among rescue workers and employees of the power station who received 2.9-16 Gy (290-1600 rads). Three others died of different causes. The surviving workers show a 15-30% lower mortality from solid cancers than the general Russian population and the residents of the Bryansk district, which received the highest contamination, had a 5% lower solid tumor incidence than expected (26). Informative reviews on **molecular mechanisms of hormesis** and related phenomena may be found in the papers by Tang and Loke (32) and Brooks and Dauer (33).

It is important to compare a joint report of the French Academy of Sciences and of the French Academy of Medicine (34) on low radiation dose carcinogenic effects, published in 2005, shortly before a comparable report of BEIR VII/Phase 2 of the National Academy of Sciences-National Research Council (35) was published. Covering the same questions, the two groups of experts came to different conclusions (36). The French report finds that as epidemiological studies have been unable to detect any significant increases in cancer after radiation doses of up to about 100 mSv (10 rem), that there are no convincing data showing any increase in cancer in adults, children, or infants receiving doses under about 100 mSv (10 rem). The LNT therefore greatly overestimates the risk of these low doses. The Health Physics Society in 2010 published a position paper on this topic (PS010-2), "Radiation Risk in Perspective".

In contrast, the BEIR VII report concludes that "The committee judges that the balance of evidence from epidemiologic, animal and mechanistic studies tends to favor a simple proportionate relationship at low doses between radiation dose and cancer risk. Uncertainties on this judgment are recognized and noted." The BEIR VII report recommends the continued use of LNT at low or very low doses. However, the BEIR VII report does not consider the cancer threshold data of the radium dial watch painters or that of patients in whom Thorotrast was used as an x-ray contrast agent (liver dose of 2 Gy [200 rads] required for hepatomas). The French report does. The two groups differ in their interpretation of the results of the Hiroshima/Nagasaki Life Span Study. The French report finds no significant increase in cancer after doses below 100 mSv (10 rem), while the BEIR VII report tends to lump the low dose data with higher dose data to find cancer increases. Animal studies have not shown increased cancer at doses below 100 mSv (10 rem); many show thresholds and about 40% show hormesis. The French report points out the high efficacy of DNA repair mechanisms and apoptosis (death of damaged cells), while the BEIR VII report minimizes this research because all the biological mechanisms have not yet been worked out. An important difference between the two reports concerns *in utero* radiation. While the BEIR VII report concludes that fetal doses of 10-20 mSv (1-2 rem) caused increased levels of leukemias and solid cancers, the French report doubts a causal relationship because this represents a biased sample of fetuses in which only pregnant women with problems were subjected to x-ray studies. The randomly irradiated fetuses in the Hiroshima/Nagasaki Life Span Study showed no such cancer increase, nor have *post partum* twin studies where one was irradiated and the other was not. More detailed comparisons are in (36). It is interesting to note that the BEIR VII report was funded by the EPA, the NRC, and the NIST. As the present radiation programs of the EPA and the NRC are based upon the LNT, one wonders about the appearance of a conflict of interest.

RECOMMENDED CHANGES FOR 10 CFR PART 20

Based on the forgoing discussion, it is requested that the NRC greatly simplify and change Part 20 to eliminate the use of the LNT paradigm and take radiation hormesis into account. The following recommendations are made:

- 1) Worker dose limit should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.
- 2) ALARA should be removed entirely from the regulations, as it perpetuates radiophobia among workers and the public and makes no sense to decrease radiation doses that are not only harmless but may be hormetic.

3) Public dose limits should be raised to match worker dose limits, as these low doses may be hormetic. Low-dose limits for the public perpetuates radiophobia.

Obviously there will have to be many other changes to NRC regulations when 10 CFR Part 20 is brought up to present scientific standards. Examples include the medical regulations and low-level radioactive waste regulations. But it all needs to start with eliminating the use of the LNT model.

Thank you for your attention and consideration.

Sincerely,
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