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Comments of the Institute for Energy and Environmental Research to the Nuclear Regulatory Commission (Docket NRC-2015-0057) on the Petitions for Rulemaking (PRM-20-28, PRM-20-29, and PRM-20-30) regarding radiation risk models and permissible maximum radiation exposures to the public and to workers

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These comments relate to three petitions filed in February 2015 to the Nuclear Regulatory Commission (NRC), NRC Docket number NRC-2015-0057.² These related petitions ask the NRC to amend 10 CFR 20, the regulation that sets limits for ionizing radiation exposure to the general public, except from background radiation and radiation administered for medical purposes, and to workers at NRC regulated facilities.

The three petitions were filed by Carol S. Marcus (PRM-20-28), Mark L. Miller (PRM-20-29) and Mohan Doss, et al. (PRM-20-30). PRM-20-28 asks the NRC to change 10 CFR 20 in the following ways:³

- 1) Worker doses 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 makes no sense to decrease radiation doses that are not only harmless but may be hormetic.
- 3) Public doses should be raised to worker doses, as these low doses may be hormetic. Why deprive the public of the benefits of low dose radiation?

¹ Arjun Makhijani is president of the Institute for Energy and Environmental Research. These comments have been endorsed by Joe, Sarah, and Cynthia Sauer.

² The petitions for rulemaking were filed by Dr. Carol S. Marcus (PRM-20-28), Mr. Mark L. Miller (PRM-20-29), and Dr. Mohan Doss et al. (PRM-20-30). On the Web at <http://www.regulations.gov/#!documentDetail;D=NRC-2015-0057-0010>.

³ Marcus 2015, p. 7

4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

PRM-20-29 is very similar to PRM-20-28, but asks only for the first three of the above listed changes to 10 CFR 20, in almost identical language. It omits the fourth regarding pregnant women, embryos, fetuses and children. On the point about raising dose limits to the public to worker levels, it adds “Low-dose limits for the public perpetuates radiophobia.”⁴

PRM-20-30 simply states that “we support the changes recommended in the petition [PRM-20-28] by Dr. Marcus.”⁵

To begin with, these petitions contain a host of incorrect statements. For instance, the Doss petition (PRM-20-30) states that “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.”⁶

It is entirely wrong to say that the study of hormesis is prohibited, as evidenced by the fact that the National Academies’ 2006 BEIR VII devoted a whole appendix to it,⁷ the study was funded, among others, by the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC).

Evidently, the conclusions of the BEIR VII report (among others) was not to the liking of the petitioners. It would have been unscientific and contrary to public health protection and common sense for the authors of that report to recommend use of the hormesis hypothesis for radiation protection regulations after having concluded 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.”⁸

The Science Advisory Board of the EPA reviewed the BEIR VII report extensively; it recommended some changes in it to the EPA, which in turn published its “blue book” containing radiation risk factors in 2011.⁹

In place of a careful analysis of the matter, such as the one that can be found in the BEIR VII report, the petitioners resort to hurling epithets at the LNT hypothesis and its authors. PRM-20-28 calls the LNT hypothesis a “lie.” Despite the repeated careful study that has

⁴ Miller 2015, pdf pages 6-7

⁵ Doss et al. 2015, p. 4

⁶ Doss et al. 2015, p. 3. Similarly, despite the extensive investigation of thresholds and hormesis in various reports, including the BEIR VII report, PRM-20-28, referring to investigations that the LNT model may be wrong, claims that “[t]his is a whole field of science that regulators pretend does not exist (Marcus 2015, p. 3).

⁷ NAS-NRC 2006, Appendix D

⁸ NAS-NRC 2006, p. 6

⁹ EPA 2011

been devoted to the subject, it claims that “[t]here was no science here. The LNT is based on hogwash.”¹⁰

Name calling does not negate the well-established, repeatedly studied carefully, and repeatedly reaffirmed hypotheses that (i) ionizing radiation is carcinogenic and (ii) increasing levels of exposure produce increased levels of cancer risk down to very low levels of exposure, with no threshold discernible.

Epidemiological studies provide only part of the evidence for the LNT hypothesis. Given the high rate of occurrence of cancer from all causes, such studies by their nature cannot by themselves provide firm evidence about the risks of radiation at very low doses of a few millirem or even a few tens of millirem of exposure. However, these studies clearly indicate linearity without a threshold up to the levels to which statistically significant conclusions are possible. Radiobiological and other evidence provide the scientific basis for extending the LNT hypothesis to very low doses. Taken together, the ensemble of scientific evidence is persuasive that there is no threshold beneath which ionizing radiation would not produce biological damage and increase cancer risk.

We will discuss just one very recent epidemiological study, which is remarkable for a number of reasons.¹¹ It was funded by government departments that promote nuclear power and make nuclear weapons and those charged with protecting health. The supporters included the two major French nuclear power corporations, AREVA and Électricité de France; both have a corporate presence in the United Kingdom and the United States. The study extends the Hiroshima-Nagasaki low dose epidemiological conclusions to well below 10 rem (100 mGy). It also provides fresh evidence that cancer risk increases linearly with dose, including for populations continuously (or quasi-continuously) exposed to ionizing radiation at low dose rates.

It was a large cohort study of over 300,000 nuclear industry workers from France, the United Kingdom, and the United States who had reliable exposure records. The study found clear evidence that solid cancer risk increases are linearly proportional to radiation exposure down to levels far below the 10 rem (100 mGy) associated with Hiroshima Nagasaki investigations. The average exposure of the workers was 20.9 mGy (2.09 rem) and the median exposure was just 4.1 mGy (410 millirem).

The study also provides evidence that the present model used for low-dose rate exposure may underestimate the risk of continuous radiation exposure. Specifically, the acute doses received by the survivors of the Hiroshima and Nagasaki atomic bombings have been postulated to produce a greater risk than the same dose accumulated over a long period of continuous exposure at low dose rates. A “dose and dose rate effective factor” is typically used to reduce the atomic bombing survivor risk estimates for application to continuous low-dose rate situations. The BEIR VII report continued this approach though in a more refined way; it reduced acute dose risks by a factor of 1.5 to estimate the risks of low dose and low dose rate ionizing radiation for solid cancers.

¹⁰ Marcus 2015, p. 3

¹¹ Richardson et al. 2015

The Richardson et al. research indicates that this approach may be incorrect – that continuous exposures to low dose rates may produce risks similar to acute exposures:

Contrary to the belief that high dose rate exposures are substantially more dangerous than low dose rate exposures, the risk per unit of radiation dose for cancer among radiation workers was similar to estimates derived from studies of Japanese atomic bomb survivors.¹²

Hence, contrary to the petitioners demand that worker exposure limits be raised to 10 rem in circumstances of continuous exposures, the Richardson et al. study points to a significantly lower exposure limits since cancer risks for a given total exposure may be underestimated by approximately the dose rate effectiveness factor. No single study can be regarded as definitive, but the reliability of the dose estimates and the health data used in the study and many other features make it an extraordinary resource both for scientific and regulatory purposes. Rather than a relaxation of exposure standards its conclusions point to the need for tightening them.

We support the EPA’s comments on the petition, including the following remarkably clear and unequivocal statement:

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.¹³

We also strongly support the EPA conclusion that the NRC should deny the petition. We stress that all three petitions should be denied in their entirety. In this regard, we add some comments regarding the last two of the four demands in PRM-20-28 – that (i) public exposures limits should be raised to worker exposure limits (which in turn would be raised to 10 rem per year for continuous exposure) and (ii) exposures to pregnant women, embryos, fetuses, and children be raised to that of the public – that is to the limits of workers.¹⁴

Given the evidence that exposures much below 10 rem (100 mGy) increase cancer risks for workers, and that children face much greater risks per unit of radiation than adults,

¹² Richardson et al. 2015, p. 1

¹³ EPA 2015, pdf p. 4

¹⁴ Ending “differential doses to pregnant women, embryos and fetuses, and children under 18 years of age” (Marcus 2015, p. 7) would mean making exposures to these groups equal to the limits for the public generally; those limits, in turn, are sought to be raised to 10 rem for continuous exposure situations.

with higher differential risks faced by females, analyzed in the BEIR VII report and earlier in EPA's Federal Guidance Report 13,¹⁵ there is a strong basis to lower the exposure limits for the public well below the 0.1 rem (1 mSv) per year now specified in 10 CFR 20. Whatever the uncertainties, it would be an irresponsible massive public health experiment to raise the public exposure limits even moderately, let alone 50 to 100 times as demanded in the petitions and, at the same time, abandon the requirement to keep exposures as low as reasonably achievable.

Extending the high limits to pregnant women, embryos, fetuses, and children would mean a complete abandonment of responsibility to future generations. It is not only an issue of cancer risk, when it concerns these groups. We have pointed out that that increased rates of early failed pregnancies and malformations are potential outcomes of in utero exposures in the early stages of pregnancy.¹⁶

In addition, special attention needs to be paid to internal exposure to radionuclides that cross the placenta. For instance, ingestion of radionuclides such as tritium and carbon-14 in food and drinking water can induce problems in early stages of fetal development, besides laying the foundation for a host of problems, including elevated cancer risk for the survivors. We are incorporating Chapters 4 (on children) and 7 (on tritium) of Makhijani, Smith, and Thorne (2006) as part of these comments. References to the issues discussed in this paragraph, as well as the comments on tritium below, are provided there.

Consider one possible outcome of the kind of relaxation of exposure during childhood advocated by two of the petitioners.¹⁷ The BEIR VII risk estimates for female children over the first five years point to an overall lifetime cancer risk of about 0.4 cancers per Gy (4 cancers per 1,000 rem) for acute exposure and about 0.27 cancers per Gy for continuous exposure.¹⁸ At 0.05 Gy (5 rad) per year, the current worker limit, the cumulative exposure during the first five years would be 0.25 Gy (25 rad). About 10 percent of female children so exposed (almost 7 percent in the case of continuous exposure) would be expected to get cancer as a result of their exposure even if all further exposure were reduced to zero. With cancer mortality at 38 percent,¹⁹ between 1 in 26 (1 in 38 for continuous exposure) children so exposed would die as a result of their exposure.²⁰

Such a scenario would be implausible with a regulation requiring that exposures to the public be kept as low as reasonably achievable (ALARA). But the petitioners are demanding that the ALARA requirement be abandoned on the ground that radiation

¹⁵ EPA 1999 and 2002 CD

¹⁶ Makhijani, Smith, and Thorne 2006, Chapter 4. Also see Doll and Wakeford 1997 for evidence of no threshold in cancer risk resulting from in utero exposure.

¹⁷ Marcus 2015 and Doss et al. 2015, the latter by reference to the former as noted above.

¹⁸ NAS-NRC 2006, Table 12D-1 (p. 311)

¹⁹ Derived from NAS-NRC 2006 Tables 12D-1 and 12D-2. We used the average of risk at 0 years (infant) and at the age of 5 years to calculate the lifetime cancer risk due to an exposure of 0.05 Gy per year for the first five years of life.

²⁰ The overall uncertainties (all cancers, all ages) in the BEIR VII cancer morbidity risk estimates were estimated to be about a factor of 2 on either side (NAS-NRC 2006, Table 12-13 (p. 291)).

exposure may be beneficial to health, going so far as to pose the question, apparently rhetorical, “Why deprive the public of the benefits of low dose radiation?”²¹

Should the NRC adopt the approach recommended by the petitioners, it is not difficult to imagine the proliferation of ionizing radiation salons and the return of radium-laced toothpaste and cosmetics, not to speak of radium-laced bread and chocolate.²²

Endorsing hormesis or even a threshold of cancer risk as the basis for regulation of exposure to ionizing radiation could lead to a public health disaster that would be difficult to control, especially if promoting radiation exposure becomes entrenched in the economic system. The petitioners, who exhibit a considerable amount of contempt for scientists who support the linear no-threshold view (“hogwash”, “no science here” “reminiscent of the Catholic Church at the time of Galileo”²³), have entirely ignored the possibility that they are the ones who may be wrong, that their speculation that “radiation *may* be hormetic”²⁴ could lead to widespread illness, dislocation, and death.

There are of course uncertainties in all radiation risk estimates, as noted previously. Indeed, new evidence, notably the Richardson et al. study, indicates that the BEIR VII risks may be underestimated in the case of continuous exposure: BEIR VII estimates the risks for continuous exposure to be a factor of 1.5 less than for acute exposure; however no such reduction is indicated by the analysis in Richardson et al.

The NRC has already been negligent of its responsibility to women, including pregnant women, and children. Other than exposure limits in the radiation workplaces for women who declare their pregnancies, no special protections are in place for fetal protection for women who want to carry their pregnancies to term. Greater protections are needed.

For instance, Environmental Reports filed by the NRC’s nuclear reactor licensees report routine releases of tritium to surface waters and the atmosphere.²⁵ In the latter case, the tritium mixes with moisture and comes down as radioactive rain. We had raised this issue as a critical one to be examined by the study funded by the NRC to assess the cancer risk faced by children near nuclear power reactors.²⁶ Yet, the NRC cancelled a study that could have shed some light on this question on the ground that it would take too long and cost too much money. Two pilot studies, including one for children, of radiation risks faced by people living near nuclear facilities were underway. The total cost of both would have been about \$8 million; the estimated time would have been less than 4 years.²⁷ The children’s study alone would therefore have been much under \$8 million. For reference, nuclear power reactors generate revenues of roughly \$40 billion

²¹ Marcus 2015, p. 7

²² Crezo 2012

²³ Marcus 2015, p. 3

²⁴ Marcus 2015, p. 7, italics added

²⁵ NRC Reports, various years

²⁶ Makhijani 2012

²⁷ Arjun Makhijani, personal notes taken on 12 November during the NAS Nuclear and Radiation Studies Board meeting on November 12, 2015.

per year²⁸ – or \$120 billion over 3 years. The latter figure is 15,000 times the total cost of both cancer studies and an even larger factor greater than the children’s study alone.

Finally, we note that the EPA has the authority to set limits for public exposure to radiation. The EPA has unequivocally asked the NRC to deny the petition on the ground that ionizing radiation is a known carcinogen and that there is no threshold to radiation cancer risk. The NRC also has the legal responsibility to protect public health under the Atomic Energy Act. We therefore conclude that the NRC is legally and scientifically obliged to completely, firmly, and unequivocally reject all three petitions in their entirety. In doing so the NRC should explicitly reaffirm the linear-no-threshold hypothesis and state clearly that it is the scientific basis of its radiation protection regulations, including the mandate to its licensees to keep radiation exposures as low as reasonably achievable.

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²⁸ The average wholesale electricity price in 2014 was \$52.36 per megawatt-hour – see <http://www.eia.gov/electricity/wholesale/#history> (EIA Wholesale 2015); nuclear generation was 797 million megawatt-hours – see http://www.eia.gov/electricity/monthly/epm_table_grapher.cfm?t=epmt_1_01 (EIA EPM 2015).

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