SARI's Response to EPA's ANPR Regarding its Standards for Nuclear Power Operations

The Federal Register dated Feb 4, 2014 http://www.gpo.gov/fdsys/pkg/FR-2014-02-04/pdf/2014-02307.pdf published an Advance Notice of Proposed Rulemaking (ANPR) requesting public comment and information on potential approaches to updating the Environmental Protection Agency (EPA)'s ''Environmental Radiation Protection Standards for Nuclear Power Operations'' (40 CFR part 190). Below is the response from Scientists for Accurate Radiation Information (SARI) to this ANPR:

These comments are from an international group of professionals called Scientists for Accurate Radiation Information (SARI), http://radiationeffects.org/. *The objective of SARI is to monitor and counter nuclear/radiological misinformation that could adversely impact the world's ability to effectively respond to nuclear and radiological challenges, to the end point of saving lives*. Our group is multidisciplinary and includes expertise in a variety of areas including radiation source characterization, radiation transport, external and internal radiation dosimetry, radiobiological effects (both harmful and beneficial), dose-response modeling, radiation risk and benefit assessment, nuclear medicine, diagnostic radiology, radiation oncology, commercial nuclear power, technology supporting use of nuclear power, isotope production, and nuclear/radiological emergency management.

EPA's current regulations relating to radiation safety are based on the linear no-threshold (LNT) hypothesis for radiation-induced cancers or the concept that even very low doses of radiation can cause cancers, resulting in the setting of very low radiation dose limits for the public. The first enclosed document entitled "Comment to EPA on its standards for nuclear power operations" discusses the current state of the art in the field of low-dose radiation health effects, and shows that accumulated evidence neither supports the LNT hypothesis for radiation-induced cancers nor the concept that low-dose radiation causes cancers. Hence, regulating radiation dose at low levels would not be protecting health or minimizing danger to life, but would tend to diminish health and endanger life.

The second enclosed document, entitled "Comment to EPA on the Importance of Considering Dose-rate and Dose Fractionation in Setting Dose Limits", discusses the importance of taking into consideration the period over which radiation exposure occurs, for estimating the health effects of radiation. Illustrative examples of evidence are presented to show that the same cumulative radiation dose can result in excess cancers when received acutely whereas when received over an extended period of time it can be cancer curative. Hence, radiation dose limits, when they are defined without specifying the period of exposure, would not be protecting health or minimizing danger to life.

The above comments and the enclosed documents apply not only to the current ANPR regarding 40 CFR Part 190 but also to the overall framework of radiation safety regulations of EPA. Prompt action is advisable in modifying EPA radiation safety regulations taking these concepts into consideration, so that EPA can truly perform its Congressional mandate to protect health and minimize danger to life.

Thank you for your consideration.

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on behalf of Scientists for Accurate Radiation Information (SARI)

Comment to EPA on its standards for nuclear power operations

The bases for the existing EPA standards relating to public radiation dose limits are described in the Federal Register notice: http://www.gpo.gov/fdsys/pkg/FR-2014-02-04/pdf/2014-02307.pdf. In the Background section it states (bolding of text is by the authors of the Comment):

> *Section 161(b) of the Atomic Energy Act of 1954 (AEA) authorized the Atomic Energy Commission (AEC) to ''establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or* ***to protect health or to minimize danger to life*** *or property[.]'' 42 U.S.C. 2201(b) (1958).*

This authority was transferred to EPA in 1970, as per the subsequent text. Finally, it says:

> *Relying on this authority, EPA promulgated standards in 1977 to protect the public from exposure to radiation from the uranium fuel cycle at 40 CFR part 190, ''Environmental Radiation Protection Standards for Nuclear Power Operations.''*

Thus the mandate to the EPA by the US Congress is to take actions **to protect health or minimize danger to life**. EPA's actions in this area in 1977 were based on the concept that even the smallest exposure to radiation increases the risk of cancer. This concept for predicting cancer risk from radiation, known as **the linear no-threshold (LNT) hypothesis**, was adopted by the National Academy of Sciences (NAS) in 1956 (Calabrese, 2013). On this basis, complying with EPA's very small radiation dose limits to the public would **protect public health and minimize danger to life**. These dose limits also applied to accumulated doses, over time, from low dose-rate exposures.

The primary data used by the NAS for predicting low-dose radiation health effects are the atomic bomb survivor data. For example, the BEIR VII report (NRC, 2006) on p. 141 refers to these data as "the single most important source" for evaluating the cancer risk from low-dose radiation. The conclusion of the report, on p. 323, states: "The committee concludes that the current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans." This conclusion, irrespective of the exposure mode, implies that the smallest radiation dose increases the risk of cancer. Indeed, it supports the very low dose limits set by EPA in 1977 for members of the public.

The atomic bomb survivor data, based on acute radiation exposures, have also been described as the "gold standard" for determining health effects of low-dose radiation by influential scientists (Hall and Brenner, 2008). The reported excess cancers in the low-dose cohorts among the atomic bomb survivors have been used to raise concerns about the radiation dose from CT scans (Brenner and Hall, 2007). Indeed, the atomic bomb survivor data are the most frequently cited source for the current widespread cancer concerns regarding low-dose radiation.

However, the latest update to the atomic bomb survivor data (Ozasa et al., 2012) is qualitatively different from the previous reports (Preston et al., 2003, Preston et al., 2007) in that the new dose-response data for cancer mortality has a significant curvature, as indicated by the authors' statement on p. 234 that "the curvature over the 0–2 Gy range has become stronger over time, going from 0.20 for the period 1950–1985 to 0.81 for 1950–2003, and has become significant with longer observation (Table 7)." The curvature is discussed on p. 238: "The apparent upward curvature appears to be related to relatively lower than expected risks in the dose range 0.3–0.7 Gy (Fig. 4), a finding without a current explanation." The LNT hypothesis, used to fit the atomic bomb survivor data, does not explain the reduction of cancers in this low dose range. When a hypothesis does not fit the data, the Scientific Method requires that it be rejected, and so the predictions of excess cancer risk for low doses (Ozasa et al., 2012), based as they are on the LNT hypothesis, cannot be considered valid. On the other hand, if the reduction of cancers in the lowest dose cohorts is due to the up-regulation of adaptive protection (Feinendegen et al., 2004, Feinendegen et al., 2013), the baseline cancer rates used in the atomic bomb survivor data analysis (Ozasa et al., 2012) would have a negative bias. Correcting the negative bias would result in a dose-response curve consistent with the concept of radiation hormesis (Doss, 2012, Doss, 2013), which would therefore imply that low-dose radiation reduces rather than increases cancer risk. There is, indeed, considerable evidence already for the cancer-preventive effect of low-dose radiation (Kostyuchenko and Krestinina, 1994, Cuttler and Pollycove, 2003, Sakamoto, 2004, Hwang et al., 2006, Tubiana et al., 2011).

The qualitative change in the atomic bomb survivor data—that they no longer provide the evidence for low-dose radiation carcinogenicity—has been recognized *de facto* by influential scientists in the field, since they do not refer to the latest atomic bomb survivor data (Ozasa et al., 2012) to raise cancer concerns. Rather, they refer to older data (Preston et al., 2007), irrespective of the mode of exposure, as seen in their publications, e.g. (Brix et al., 2013, Miglioretti et al., 2013, Brenner, 2014, Brix and Nekolla, 2014, Cucinotta, 2014, Steward et al., 2014). We would add that, in a recent debate on the health effects of low-dose radiation (Doss et al., 2014), the proponent of low-dose radiation carcinogenicity, in his opening statement, did not refer to the latest atomic bomb survivor data but cited older data, and that too only indirectly. This contrasts with a previous debate (Little et al., 2009) where the atomic bomb survivor data were given a central role. In the Rebuttal, the proponent again did not cite the newer data but referred to older atomic bomb survivor data to claim absence of threshold or hormetic dose-response.

Thus, the primary data used for low-dose cancer risk assessment in the BEIR VII report (and in other advisory body reports) are no longer a valid justification for the concerns. On the contrary, there is considerable support for using a threshold concept for radiation protection, based on the evidence of threshold or hormetic dose-response for the effect of radiation, both after acute and low dose-rate exposures (Kostyuchenko and Krestinina, 1994, Sakamoto, 2004, Hwang et al., 2006, Tubiana et al., 2011, Doss, 2013, Cuttler, 2014). Hence the EPA's low dose limits, which are based on the LNT hypothesis, **neither protect public health nor minimize danger to life**.

A very harmful consequence of any low dose limit is that it reinforces the public perception that low-dose radiation is very dangerous, resulting in the "precautionary" actions that contribute to increased deaths. A recent example is Fukushima where many deaths were caused by the emergency evacuation of hospitals and nursing homes and the prolongation of the evacuation for years, mostly due to the low-dose radiation concerns (Ichiseki, 2013, Nomura et al., 2013, Saji, 2013, AJW, 2014). Precautions because of low-dose radiation concerns in diagnostic imaging may also be harming patients: poor quality images due to dose reduction, physicians not ordering diagnostic studies when indicated, patients withholding consent for such imaging studies, etc. (McCollough, 2011, Boutis et al., 2013, Goske et al., 2013, Pandharipande et al., 2013, Brody and Guillerman, 2014).

Since the mandate to EPA is to take actions to protect health or to minimize danger to life, and since the current low dose limits do not protect public health or minimize danger to life based on the above discussion, the EPA's low dose limits cannot be justified under the present law. These limits have to be raised as high as reasonably safe, in order to satisfy the mandate of the Congress and comply with the laws of the United States.

Whereas EPA may have previously utilized advisory body reports, such as BEIR VII, for guiding its actions, the new atomic bomb survivor data have negated the conclusions of these reports. They can no longer be used as the current state of the art in this field. There is no requirement for the EPA to follow the guidelines of international or national advisory bodies. If it had no scientists but only administrative and management staff, EPA would be excused for ignoring the new atomic bomb survivor data and the low-dose-rate exposure data, and making no changes to its dose limits. However, EPA does have a considerable base of scientific expertise and is able to evaluate the current literature and reach the conclusions that we have.

We strongly urge EPA to fulfill its mandate to **protect public health and minimize danger to life** by using the latest data and scientific information, and by rejecting old reports whose conclusions are no longer valid.

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Comment to EPA on the Importance of Considering
Dose-rate and Dose Fractionation in Setting Dose Limits

The EPA's public radiation dose limit is 0.25 mSv per year for nuclear energy related operations. This low limit is based on the linear no-threshold (LNT) hypothesis for predicting the cancer risk from low-dose radiation that was adopted by the National Academy of Sciences (NAS) in 1956. It presumes that even the smallest dose of radiation increases the risk of cancer death. We would like to demonstrate again why such a low dose limit is unreasonable. In doing so, we have selected just a few illustrative examples from a large number of reports of epidemiological, clinical and experimental investigations. We are aware of the complexity of the mechanisms involved in the biological effects of low dose-rate exposures and repetitive low dose treatments. The studies cited here on humans, who received low dose-rate radiation in the environment or fractionated radiation exposures in therapeutic medicine, reveal the invalidity of modeling the risk of cancer or other health detriment as a linear function of accumulated dose. All of these data contradict the predictions of the LNT hypothesis for assessing risk, the method recommended by national and international radiation protection organizations. This 1956 hypothesis, which suggests keeping exposures as low as reasonably achievable (ALARA) to minimize risk, is still the basis for the EPA policy of setting limits for radiation exposures in order to protect health or minimize danger to life.

No evidence of increased cancer mortality in areas of high background radiation

The natural background radiation level in the USA ranges from about 1 to more than 20 mSv per year (NCRP, 2009). Figure 1 indicates that people who live in areas of higher background radiation do not have an increased risk of cancer mortality (Frigerio et al., 1973). So there is no justification for setting the current public radiation dose limit at 0.25 mSv/year as it would not **protect health or minimize danger to life.**

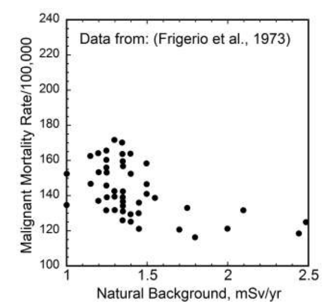

Figure 1. Cancer mortality rates vs. Background radiation in the USA

Dose-rate and dose-fractionation considerations

The carcinogenicity of a high dose of radiation was established in the study of the atomic bomb survivors. However, they were exposed instantaneously. When organisms are exposed to radiation continuously over an extended period of time, it is well known that they adapt to this stress by up-regulating their protective systems, which prevent, repair or remove cell and tissue damage and maintain organ function and health (Fliedner et al., 2012). For the case of radiation cancer therapy, though the total dose given to the tumor and incidentally to the surrounding tissues is quite high, being in the range of 20-80 Gy, using dose fractions allows the body's protective systems to repair (or replace) damaged cells/tissues during the period between the dose fractions. Different from tumor cells, the normal tissues suffer less damage and side effects in comparison to similar doses given acutely in a short time. These real-life experiences contradict the radiation protection LNT methodology of summing radiation doses over prolonged periods to calculate DNA damage and predict cancer risk (Mitchel, 2007).

Another example of the different response obtained, when a recovery time interval is provided between radiation exposures, is the systemic treatment of cancers using low-dose total body irradiation (LD-TBI) (Chaffey et al., 1976, Choi et al., 1979). In these clinical studies, a total whole body dose of 1.5 Gy was delivered in comparatively small fractions over a period of five weeks. This treatment resulted in similar or better success in curing cancer, compared to chemotherapy (see Figures 2 & 3 –

Figure 2 shows no statistically significant difference, while Figure 3 shows better success with LD-TBI.) (Chaffey et al., 1976, Pollycove, 2007). The same dose, given instantaneously, is known to

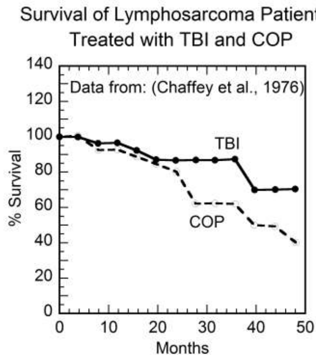

Figure 2. Comparison between LD-TBI and matched COP-treated groups. Differences between groups are not statistically significant.

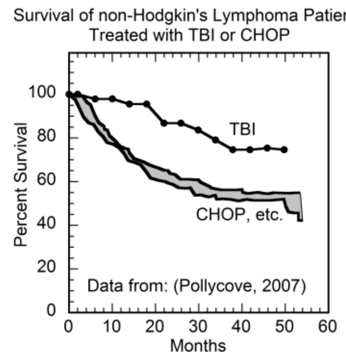

Figure 3. Comparison of LD-TBI with chemotherapy for patients with non-Hodgkin's lymphoma

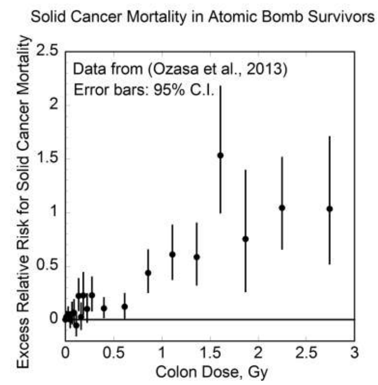

Figure 4. Solid cancer mortality in atomic bomb survivors as a function of dose.

increase cancer mortality from the follow-up of the atomic bomb survivors (see Figure 4) (Ozasa et al., 2013). The low-dose treatments exploit not only the capability of normal cells to enhance protection against immediate damage but also the up-regulation of the adaptive protection systems over extended periods of time (Feinendegen et al., 2013).

Thus, dose-rate and dose fractionation are very important considerations in determining the health effects of radiation. Since the risk of losing very important beneficial health effects of dose-rate and dose fractionation are not considered in setting the public dose limits, the present dose limits would not only fail to **protect health or minimize danger to life**, but would actually endanger health and increase the danger to life**.**

We urge EPA to consider the effects of dose-rate and dose-fractionation in setting public radiation dose limits.

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