Scientists for Accurate Radiation Information (SARI) XLNT Foundation

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Comments from SARI and XLNT Foundation on the ICRP draft "Radiological Protection of People and the Environment in the Event of a Large Nuclear Accident"

Here are some facts and recommended actions regarding ionizing radiation:

1. High radiation doses in a short period of time (known as acute radiation doses) can increase cancer risk, as observed in the atomic bomb survivors (Ozasa et al., 2012). Such high acute radiation exposures should be avoided to keep everyone safe. Though the Ozasa et al. publication claimed that their data are consistent with the linear no-threshold (LNT) model, and so low radiation doses would also increase cancer risk, other analyses have shown that there are major flaws in the Ozasa et al. analysis and that their data are not consistent with the LNT model but consistent with radiation hormesis, i.e., the concept that low radiation doses reduce cancer risk (Doss, 2012, Doss, 2013, Sasaki et al., 2014). There is considerable additional evidence to support radiation hormesis (Doss, 2018).
2. Even high radiation doses, equivalent to 1500 mSv received in small acute doses during the period of five weeks, have resulted in a cancer therapeutic effect and not a carcinogenic effect (Chaffey et al., 1976, Choi et al., 1979, Sakamoto, 2004, Pollycove, 2007). Therefore, if the radiation exposures are over extended periods of time, there should be no concerns regarding radiation doses much higher than the current annual public radiation dose limit (1 mSv) which has been set based on the LNT model. Therefore, the annual public radiation dose limit should be raised.

For the purposes of radiation protection, the ICRP uses the LNT model, claiming that even the lowest radiation dose can increase cancer risk (Section 2.2.1.2. Cancer and heritable diseases, page 12, line 305 in the ICRP Draft Document). If the LNT model were valid, protection of the public would become very difficult in the case of a large nuclear accident which released large amounts of radioactive materials into the atmosphere or into the ocean, despite their dispersal and dilution, because even the lowest radiation doses would be of concern. On the other hand, if the LNT model is not valid, and the concept of radiation hormesis is valid, then the low radiation doses resulting from the nuclear accidents would not be of concern. Therefore, the key question is: Is the LNT model valid or is radiation hormesis valid? ICRP and other advisory bodies have failed to resolve this question as they have routinely ignored the vast number of studies that provide evidence for radiation hormesis and have accepted faulty studies that support the LNT model (Doss, 2018, Doss, 2019a).

The latest advisory body document to recommend the use of the LNT model for radiation protection is the NCRP Commentary No. 27 (NCRP, 2018) but this document has been refuted (Doss, 2018, Ulsh, 2018, Doss, 2019a, Doss, 2019b). Though the NCRP has responded (Shore et al., 2019) to one of the refutations, it has not addressed the criticisms as explained in the unpublished Letter to the Editor that is annexed to these comments (see Page 5).

Even a brief, nontechnical examination of the NCRP Commentary No. 27 would show that there is no validity to the claim of the Commentary regarding the LNT model. To illustrate this, let us discuss the first study that the NCRP Commentary claimed to provide strong support for the LNT model, the study of solid cancer incidence among the atomic bomb survivors (Grant et al., 2017). The abstract of this publication states that uncertainties in the shape of the dose response preclude definitive conclusions to confidently guide radiation protection policies. In view of such an indeterminate conclusion by the authors, this study would not provide support for any dose-response model. Even a nontechnical person can conclude from reading the abstract that this study does not provide any support for the LNT model, and certainly does not provide strong support for the LNT model.

There must be a reason for such an egregious error committed by the NCRP. Have any supporters and beneficiaries of the LNT model (other advisory bodies, regulatory agencies, professional organizations, etc.) pointed out this major error (which would be obvious even to a nontechnical reader)? There must be a reason such a major error by the NCRP has been ignored and not pointed out by the beneficiaries of the LNT model. These reasons need to be investigated by committees appointed by governments so that they can get to the bottom of the issue. The governments would be justified in taking corrective actions to avoid such errors by major advisory bodies and the neglect of such errors by other advisory bodies, regulatory agencies, and professional organizations which benefit from such errors.

The LNT model has resulted in a large amount of make-work projects which do not benefit the public but would benefit the proponents of the LNT model due to the increased work/income, limelight, prestige, etc. In fact, the recommendations published in documents produced by such make-work projects have harmed the public by creating unnecessary radiophobia and inducing governments to undertake dangerous actions such as the evacuations in Fukushima. No lives were lost due to the radiation exposures from the nuclear accidents in Fukushima, and none would have been lost if there had been no evacuations. The actions taken by the governments and the public due to the radiophobia caused by the recommendations of the ICRP, e.g., public radiation dose limit of 1 mSv per year based on the LNT model, did cause many fatalities. The ICRP should withdraw such ill-advised and dangerous recommendations.

The ICRP should rewrite the draft document based on the observed health effects of exposure to low-level radiation rather than the extrapolation of high dose data to low doses. It is not logical to determine the health effect of taking a single caplet of medicine by extrapolating the health effect of taking 50, 100, 200, 400, etc. caplets at a time, though it would be mathematically simple and convenient to do. It would be very unwise and dangerous to take actions based on such extrapolations. In a similar manner, the use of the LNT model for radiation protection is illogical, unwise, and dangerous. Also, why is an extrapolation needed when there is over one hundred years of data on the health effects of low radiation exposures, and none of the studies with low radiation exposures have shown any deleterious effects, while extrapolation from high dose data would indicate detriment?

The ICRP should consider the above, discontinue the use of the LNT model, discontinue the recommendations of low annual public radiation dose limits, and limit its discussions to avoidance of high radiation doses to the radiation workers and the public in the case of nuclear accidents.

It would also be appropriate for the ICRP to apologize to the public for having misled them and the governments about the cancer risk from low levels of radiation by using the LNT model for many decades, and for being a major contributing factor to the fatalities caused by the evacuations in Fukushima and Chernobyl.

Sincerely,

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Note: All the signers of the above comments are members or associate members of SARI (Scientists for Accurate Radiation Information, http://radiationeffects.org/) or members of the XLNT group, https://www.x-lnt.org/xlnt-group. 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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Letter to the Editor submitted to Journal of Radiological Protection (JRP), but rejected by JRP with the following comment: “Continued correspondence on the same subject is discouraged as it tends to be unproductive and is not the most constructive means of addressing an issue.”

FYI: Below is the Letter I submitted to JRP:

Comment on the Response by Shore et al to the Letter to the Editor by Doss Regarding the NCRP Commentary No. 27

Dear Editor,

I am writing with reference to the response by Shore et al. (Shore et al., 2019) to my Letter to the Editor (Doss, 2019b) regarding the Memorandum by Shore et al. (Shore et al., 2018) summarizing the NCRP Commentary No. 27 (NCRP, 2018).

In the opening sentence of their response, Shore et al. characterize me as “a fervent writer of letters to journals, declaring his conviction that low-level exposure to ionising radiation protects against cancer (so-called ‘radiation hormesis’)”. This statement misrepresents my letters to journals because they do not declare my conviction but rather bring forth evidence for radiation hormesis that is neglected by articles which claim that low-level exposure to ionising radiation increases cancer risk. The derogatory reference to radiation hormesis in this sentence also misrepresents the present status of radiation hormesis in the scientific literature since much of the published evidence for radiation hormesis has not been refuted, in contrast to the published evidence for the LNT model.

Shore et al refer to my assertion regarding the atomic bomb survivor cancer incidence data (Grant et al., 2017) that Grant et al forced the statistical fit to assume a linear nonthreshold shape, and state that I am incorrect because Grant et al also considered linear-quadratic dose-response model. However, the linear-quadratic model does collapse into a linear-nonthreshold model for low doses because the quadratic term becomes negligible compared to the linear term. Therefore, my assertion is indeed correct for low doses.

Shore et al then refer to the significant difference between the male and female dose response shapes in this study as something that can be ignored at this time (they said “too much should not be read into this difference until it is better understood”) to sustain the claim that these data strongly support the LNT model. However, examination of the Table E1 of the Grant et al publication shows that there is a major qualitative difference between the female and male excess relative risks (ERRs) for cancer incidence for doses below 0.8 Gy (Figure 1).

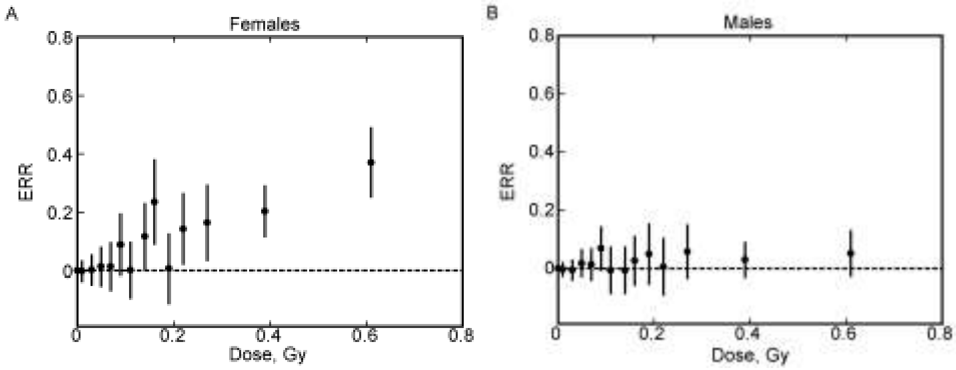

Figure 1. Excess relative risk for cancer in atomic bomb survivors for (A) Females and (B) Males. Data from (Grant et al., 2017). Error bars indicate 95% confidence intervals.

Whereas the female data are consistent with the LNT model, the male data are consistent with no increase in the ERR in this dose range and so the male data do not support the LNT model. When half of the data do not support the LNT model, it would not be correct to claim that these data strongly support the LNT model. NCRP should not have cited these data as providing strong support for the LNT model since this is not a minor matter and since it is unclear if this issue would be resolved.

Shore et al. also state that Grant et al found no firm evidence of a dose threshold for either sex. However, they failed to mention that for males, the best estimate for dose threshold was quite high at 0.75 Gy with a very large uncertainty leading to the conclusion that the dose threshold was not significantly different from zero. Considering the very large uncertainty, no conclusion can be drawn about the dose threshold for the male data from this study and so it would be wrong to claim that these data support the no-threshold model.

Shore et al then state that Grant et al reported a statistically significant positive dose-response for solid cancer over the dose range of 0–100 mGy for the entire cohort, as if this provides evidence for the LNT model. However, Grant et al state “We note the LSS male dose response over the lowest dose range considered (0–100 mGy) tended to be considerably greater than the estimates that consider broader dose ranges (Table 6). This highlights the uncertainties in the shape of the dose response in the current analyses”. Thus, the significant positive dose-response over the dose range of 0-100 mGy appears to be an indication of a problem or inconsistency in the data or analysis rather than evidence for the LNT model as Shore et al suggest.

When a model is used to fit the data, claim cannot be made that the model fits the data when it fits a very small part of the data (as NCRP has claimed) while the rest of the data are inconsistent with the model. According to the LNT model, the smallest increase in radiation dose increases cancer risk. The flat dose response when the dose increases by a large amount in the 0.2-0.75 Gy range is inconsistent with the LNT model’s contention that the smallest increase in radiation dose increases cancer risk.

As seen in the discussion above, Shore et al have not rebutted my criticisms and have grossly misrepresented the data from Grant et al in trying to justify their claim that this study strongly supports the LNT model.

Shore et al then question my explanation that the reported linear dose-response in the INWORKS study (Richardson et al., 2015) is likely due to confounding by smoking, since the higher radiation dose part of the cohort was predominantly from the earlier years (Thierry-Chef et al., 2015) when smoking prevalence rates were much higher (Graham, 1996, Centers for Disease and Prevention, 1999). They claim that based on my explanation, if lung cancers were excluded, a weaker dose-response would be expected, and this was not evident. As evidence, they state that point estimates of the excess relative risk (ERR) of solid cancer per Gy with and without the inclusion of lung cancer were virtually identical at 0.47 and 0.46, respectively. One major issue with their claim is that the point estimates had very large 95% confidence intervals of (-62% to +68%) and (-76% to +85%) respectively. If the point estimates had tight 95% confidence intervals, the virtually identical point estimates could have been used in the argument as Shore et al did. However, the point estimates had very large 95% confidence intervals and so the virtually identical point estimates could have been due to the large statistical errors even though the dose response was slightly weaker when the lung cancers were excluded. Considering that lung cancer typically accounts for approximately 30% of all cancer deaths (Boring et al., 1992), the effect of excluding lung cancer from all cancers on ERR/Gy would be too small to detect in view of the large statistical errors in the ERR/Gy values. Hence, the argument used by Shore et al and by the INWORKS study to exclude confounding by smoking is invalid.

It is well known that smoking increases not only lung cancer risk but also the risk of many other cancers (Taghizadeh et al., 2016). The INWORKS study reported that when all smoking-related cancers were excluded, the ERR/Gy was not significantly greater than zero. Thus, when the confounding effect of smoking was removed, the data did not support the LNT model. However, a large fraction (70%) of cancer deaths were excluded reducing the statistical power, and this may be the reason for the indeterminate result noted.

For French nuclear workers, an analysis (Richardson et al., 2014) has shown that smoking was indeed a confounding factor in lung cancer mortality rates. Hence, since smoking increases the risk of many other cancers and all cancers also, it may not be reasonable to claim that smoking did not confound the all cancer rates. Even a small correction for the much-increased smoking rates of the higher dose cohort would make the ERR/Gy not significant. A larger correction would tend to make these data consistent with radiation hormesis. Thus, the INWORKS study is deficient in a major way because it did not correct for the confounding effect of smoking, and so the study cannot be considered to provide strong support for the LNT model.

With reference to my comments regarding the Massachusetts TB patient study (Little and Boice Jr., 2003), Shore et al state that the study "specifically compared the linear and quadratic dose-response models and found a significantly better fit for the linear model". Since the dose bin utilized in this study (1 Gy) was large, and the range of doses considered was very large (0 to 6.4 Gy), the study did establish the linearity of dose response for large doses. However, this analysis could not provide any information on the shape of dose response at low doses, where hormetic or threshold effects would be observed. Regarding the Canadian TB patient study (Miller et al., 1989), they state that the study "tested linear and linear-quadratic dose-response models, again finding the linear model provided the better fit". For this study also, since the dose range over which they fitted the data was very large (0 to >10 Gy), the analysis does support the LNT model for high doses. For detecting the presence of a dose threshold at low doses, the data at low doses should be examined. Such an examination would show that for doses below 0.69 Gy, no significant increase in breast cancer risk was observed (Table 1 of the publication). Though Shore et al claimed that eight other epidemiologic studies (Preston et al., 2002) showed support for the LNT model, these studies also relate to high radiation dose ranges (0 to 5 Gy being the lowest dose range and 0 to 50 Gy being the highest) and so shed no light on the shape of the dose response at low doses.

Regarding my statement that significant curvature of dose-response in atomic bomb survivors irradiated in utero or in youth is inconsistent with the LNT model because such curvature indicates there is no increase in cancer risk or decrease in cancer risk for a large increase in dose, Shore et al state "Doss asserts that the solid cancer data from the Japanese atomic-bombing survivors irradiated in utero did not fit a LNT model because the dose-response curve flattened out (at an elevated level of risk) at doses above 2 Sv; this neither invalidates a LNT model at the lower doses of interest nor implies a dose threshold". My statement on curvature refers to the dose range of 0-2 Sv, since the Grant et al publication performed the curvature analysis for that dose range and not for doses above 2 Sv as Shore et al stated.

Regarding the pooled analysis of thyroid cancers (Lubin et al., 2017) for which I expressed the concern that thyroid cancer is subject to a large overdiagnosis due to screening, Shore et al pointed out that for the two largest studies, a sensitivity analysis showed that there was no confounding by screening. I concede that screening may not have confounded the dose response of this pooled analysis. However, a major issue with the use of thyroid cancer incidence as an indication of detriment is that thyroid cancer is self-limiting in the young, as explained in a recent review, and the treatment of thyroid cancer detected through screening programs has not reduced thyroid cancer mortality rates (Takano, 2017). Therefore, the pooled analysis should have examined thyroid cancer mortality as an indication of harm rather than thyroid cancer incidence. The study of thyroid cancer incidence does not provide valid information on the detriment due to radiation because of its self-limiting nature in the young and the large overdiagnosis.

Then Shore et al criticize the studies I had referred to as evidence for radiation hormesis by stating “However, most of his ‘considerable amount of epidemiologic evidence’ cannot be regarded as sound, and much of that evidence consists of””….. “comparisons of risks between study cohorts and the general population. Such evidence is weak and/or biased because: (1) the reported SMRs/SIRs do not evaluate the dose-response, and (2) it is well known that many SMRs/SIRs are biased downwards because occupational cohorts tend to be selected for good health compared with the wide range of health status in the general population.” However, the cohorts compared in the studies that I cited to support radiation hormesis are TB patients vs. TB patients (Davis et al., 1989), male radiologists vs. male doctors (Berrington et al., 2001), radiation workers vs. non-radiation workers (Sponsler and Cameron, 2005), residents of apartments vs. Taiwanese population (Doss, 2018), cancer patients vs. cancer patients (Sakamoto, 1997, Tubiana et al., 2011), and atomic bomb survivors vs. atomic bomb survivors (Doss, 2013, Sasaki et al., 2014). None of these studies compared cancer rates in occupational cohorts with those in the general population. Therefore, NCRP’s criticism is baseless. Whereas the SMRs/SIRs do not evaluate dose response, since the cohorts considered were exposed to low-dose radiation once or multiple times, the significant reduction of SMR/SIR for the cohorts indicates such low-dose radiation exposures have a cancer preventive or therapeutic effect, contradicting the LNT model according to which the cancer risk should have increased.

Shore et al state “Further, we emphasised that we chose studies for our evaluation that had to meet a minimum level of quality in terms of study design and methodology”. NCRP should have listed the studies that they considered and rejected, with brief notes describing the reasons for not utilizing the studies, especially for the studies that supported radiation hormesis and/or contradicted the LNT model. The absence of discussion of such studies makes the NCRP Commentary a very biased document (Doss, 2019a).

Whereas Shore et al criticized my Letter to the Editor without any justification as explained above, they did not address some of the points I raised regarding the NCRP Commentary: (a) the large potential errors/uncertainties in the use of the atomic bomb survivor data at very low doses for determining the shape of dose-response (b) the invalidity of negative control to exclude confounding by smoking in the INWORKS study in view of the observed hormetic effect of low-dose radiation in other studies, and (c) the invalidity of considering only breast cancer for determining detriment due to low-dose radiation when there is observed reduction of other cancers and all cancers for the Massachusetts TB patient cohort.

In summary, though it appears as if Shore et al rebutted my criticism of their summary of the NCRP Commentary No. 27, a closer examination shows that they did not address my criticism and gave invalid reasons to reject my arguments.

Shore et al state “George Box observed astutely that ‘all models are wrong but some are useful’”. By this statement, Shore et al appear to imply that the LNT model is useful even if it is wrong. I disagree. The LNT model has proven to be extremely harmful because of the actions taken by the public and/or the governments due to the resultant radiophobia, i.e. the irrational fear of low levels of radiation. For example, in Fukushima, evacuations which averted very low radiation doses (UNSCEAR, 2013) resulted in immediate deaths to hospital patients (Tanigawa et al., 2012).

A major harm from the use of the LNT model is that it blocked the study of radiation hormesis for cancer prevention when it was proposed by T.D. Luckey in 1980 (Luckey, 1980). The evidence I have quoted for radiation hormesis indicates substantial reduction of cancer mortality rates (e.g. ~20%) may be achieved by using radiation hormesis. Considering the annual worldwide cancer mortality rate of ~10 million (Bray et al., 2018), approximately 2 million cancer deaths per year could have been prevented using radiation hormesis. Hence, over 5,000 cancer deaths per day worldwide may be attributable to the use of the LNT model for radiation protection. This is a huge toll the world is paying on account of the LNT model.

Another consequence of radiophobia is that it has resulted in a very injudicious allocation of resources and tremendous expenditures with little benefit to the public (Cohen, 1987). It should be noted that these tremendous expenditures have benefitted the entire radiation protection infrastructure that has been established under the guidance of advisory bodies such as the NCRP. The beneficiaries include the advisory bodies, regulatory agencies, professional organizations, radiation protection industry, radiation protection workers, scientists who work on the LNT model, etc. This conflict of interest has never been acknowledged by the beneficiaries of the LNT model when they have supported the model in their publications.

NCRP’s Congressional Charter states that its purpose is “to collect, analyze, develop, and disseminate in the public interest information and recommendations about protection against radiation ….”. As explained above, NCRP has conducted a very biased review by omitting consideration of much of the evidence for radiation hormesis which invalidates the LNT model, by uncritically accepting invalid evidence for the LNT model, and by making claims that the atomic bomb cancer incidence data strongly support the model when they clearly do not. By its actions, NCRP has misled the public and professionals about the health effects of low-dose radiation and so the NCRP’s actions are not in the public interest. NCRP has violated its Congressional Charter.

Finally, Shore et al state that “we endeavoured to conduct a comprehensive, balanced and detached review of the evidence available from recent epidemiological studies, and concluded of the LNT model ‘that at this time no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes’”. Considering the harm to the public caused by its use, the LNT model has proven to be neither pragmatic nor prudent. Since the NCRP has not been able to discredit the published evidence for radiation hormesis, it should declare that the LNT model is invalid, radiation hormesis is valid, and terminate its operations since it has misled the public for many decades on the health effects of low-dose radiation violating its Congressional Charter, and since the use of the LNT model has caused tremendous harm to the public. This would be in the best interests of the health and welfare of the public.

Yours faithfully,

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Disclaimer

The views and opinions expressed in this article are those of the author and do not necessarily reflect those of his employer.

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