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General Comment

Please see enclosed file.

Attachments

Suggested_Approach_to_Radiation_Protection_Regulations_in_the_Post-LNT-Model_Era

Suggested Approach to Radiation Protection Regulations in the Post-LNT-Model Era

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In view of the considerable amount of evidence against the linear no-threshold (LNT) model and for radiation hormesis (see e.g. comment submitted by me to NRC https://goo.gl/va5qnF), how should we regulate radiation use? We need to identify the types of radiation exposures that can cause harm (e.g. radiation-induced cancers, as discussed below), and establish regulations to prevent such radiation exposures.

Regulations for Acute Radiation Exposures

For acute radiation exposures, the most important data that provide information on the health effects of radiation are the atomic bomb survivor data. These data, processed using the LNT model as an integral part of the analysis to extract excess relative risks (ERRs), resulted in the anomalous dose-response shape that is inconsistent with the LNT model, as the ERRs for cancer mortality decreased when radiation dose increased from ~0.25 Gy to ~0.5 Gy, resulting in a significant curvature in the shape of dose-response reported by (Ozasa et al., 2012). Since the lowest-dose cohorts would have a hormetic reduction of cancers, the use of these data (extrapolated to zero dose) as the baseline cancer rate in the analysis had likely led to a negative bias of the baseline cancer rates used for extracting the ERRs, resulting in the observed anomaly. When a correction is applied for this bias, a hormetic dose-response relationship is obtained (Doss, 2012, Doss, 2013) (Figure 1), with a threshold dose of about 0.75 Gy or 75 cGy. In view of the potential uncertainties, the threshold dose could be as low as 35 cGy. Applying an additional safety factor of 3, an acute dose of 10 cGy can be considered to be well below the threshold dose for increased cancers, and so safe. Therefore the suggested regulation for acute exposures would be a dose guidance level of 10 cGy.

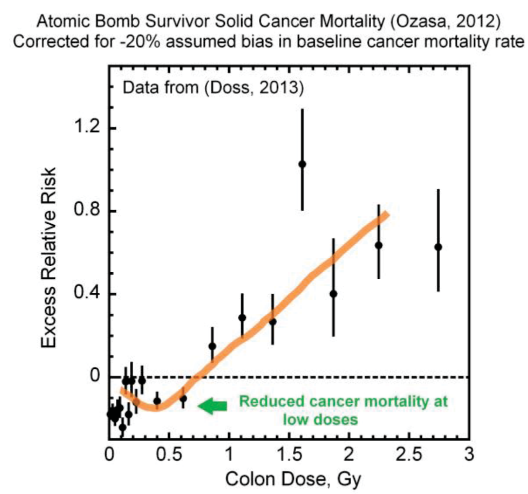

Figure 1: Excess relative risk of cancer mortality in atomic bomb survivors as a function of radiation dose, corrected for -20% assumed bias in baseline cancer mortality rate.

Regulations for Radiation Exposures Over Extended Periods of Time

Increased cancers have been observed following radiation exposures over extended periods of time also, but the threshold doses have been higher (Table 1). In addition, cumulative radiation doses, which are clearly carcinogenic in acute exposure situations, have shown a cancer preventive/therapeutic effect.

Table 1: Compilation of data on cancer risk from radiation exposures over extended time periods.

Details of Studies and Reference(s)	Duration of radiation exposure	Range of cumulative doses (Gy)	Threshold dose (Gy) for increased cancers	Cumulative dose for reduction of cancers
Thyroid cancers following diagnostic I-131 administration in children (Hahn et al., 2001)	**A few weeks**	**0-7 Gy**	**1.5 Gy**	**-**
Cancer patient survival following periodic low-dose total-body (or half-body) irradiation (Chaffey et al., 1976, Choi et al., 1979, Mendenhall et al., 1989, Sakamoto, 2004)	**5 weeks**	**1.5 Gy to 3 Gy whole body or half-body**	**2 Gy**	**1.5 Gy**
Second cancers in radiation therapy patients (Suit et al., 2007, Tubiana et al., 2011)	**6 weeks**	**0.05 Gy to 60 Gy to different parts of body**	**2 Gy**	**~0.2 Gy**
Breast and lung cancers in TB patients who underwent repeated fluoroscopic examinations (Davis et al., 1989, Howe and McLaughlin, 1996, Rossi and Zaider, 1997)	**3 years**	**0-18 Gy Chest**	**1 Gy for Breast Cancer, 2 Gy for Lung Cancer**	**~0.8 Gy for Lung Cancer**
Bone sarcomas in radium dial painters (Evans, 1974, Rowland, 1996)	**40-50 yrs**	**0-500 Gy**	**10 Gy**	**-**

The lowest threshold dose observed for increased cancers is ~1 Gy for exposure over 3 years (Howe and McLaughlin, 1996). This corresponds to ~30 cGy during 1 year. Using a safety factor of 3, dose rate of 10 cGy per year can be considered to be safe. Hence, the suggested regulation for radiation exposures over extended periods of time would be dose guidance level of 10 cGy per year.

Meaning and Use of Dose Guidance Levels

Dose guidance levels recommended in the above two sections should not be considered as dose limits, i.e. there is no requirement to stay below these dose guidance values. The term guidance means a recommendation not to exceed this value significantly in order to stay in the safe zone. Doses somewhat above guidance level would not be of concern. However, if doses exceeded the guidance levels significantly, e.g. by a factor of 2 or more, one could face increased risk of cancer, and so this should be avoided. The same dose guidance level would be applicable for radiation workers and the public, as the purpose of the regulation is to keep everyone safe. This contrasts with present regulations that penalize radiation workers with increased cancer risk (according to estimations using the LNT model which is used to set regulations) in comparison to the public.

Consequences of the New Paradigm of Radiation Protection

This new paradigm of radiation protection would reduce and eliminate the fear and concerns regarding low-dose radiation and enable/encourage prospective studies of health effects of low-dose radiation since there would not be a very low dose limit and there would no longer be any requirement to keep the radiation doses as low as reasonably achievable (ALARA). However, care in the use of low-dose radiation will be mandatory, to avoid exceeding the dose guidance levels significantly. The current radiation protection regulations and practices would not apply to potential low-dose radiation exposure situations. This would lead to considerable reduction in regulatory and compliance workforce and costs for a wide variety of radiation applications. For the activities with the potential for high radiation doses, there would be little change in the regulations.

Considering the paradigm-shifting nature of these changes, and considering the long legacy of support for the LNT model philosophy by NRC and the present advisory bodies, new advisory bodies would need to be formed with scientists who do not have the legacy of support for the LNT model to make new recommendations. The present advisory bodies would have little credibility if they recommend radiation hormesis as a basis for their recommendations, in view of their strong recommendations based on the LNT model over the past decades. Since the new regulations would require considerably less regulatory workforce within the NRC, a committee should be formed external to NRC to make the recommendations on this subject, in order to avoid conflict-of-interest issues.

The suggested changes would result in a renaissance of radiation use in health, energy, and other applications, and so there would be an increased need for radiation workers. Any staff no longer needed in the regulatory and compliance duties should be re-assigned to the new enterprises after appropriate additional training. Thus, there should not be any objections to the suggested changes based on reduced employment opportunities for the regulatory or radiation safety workforce.

Disclaimer: *These comments are the personal professional opinions of the author and do not necessarily represent those of his employer.*

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