URGENT CHANGE NEEDED TO RADIATION PROTECTION POLICY

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Abstract—Although almost 120 y of medical experience and data exist on human exposure to ionizing radiation, advisory bodies and regulators claim there are still significant uncertainties about radiation health risks that require extreme precautions be taken. Decades of evidence led to recommendations in the 1920s for protecting radiologists by limiting their daily exposure. These were shown in later studies to decrease both their overall mortality and cancer mortality below those of unexposed groups. In the 1950s, without scientific evidence, the National Academy of Sciences Biological Effects of Atomic Radiation (BEAR) Committee and the NCRP recommended that the linear no-threshold (LNT) model be used to assess the risk of radiation-induced mutations in germ cells and the risk of cancer in somatic cells. This policy change was accepted by the regulators of every country without a thorough review of its basis. Because use of the LNT model has created extreme public fear of radiation, which impairs vital medical applications of low-dose radiation in diagnostics and therapy and blocks nuclear energy projects, it is time to change radiation protection policy back into line with the data. Health Phys. 110(3):267-270; 2016

Key words: linear hypothesis; radiation protection; radiation, low-level; regulations

INTRODUCTION

FOLLOWING THE discoveries of x rays and radioactivity in the mid-1890s, many powerful medicinal properties of x rays and gamma rays were soon observed, and thousands of physicians began to cure many illnesses using these radiations in imaging and therapies. Over the past ~120 y, many tens of thousands of medical practitioners and scientists around the world have published the results of their remarkable treatments and studies in peer-reviewed medical and scientific journals. The early radiologists, who received repeated exposures, suffered from burns (early effects) and an incidence of neoplasms (late effects) significantly higher than that of comparable people who had not been exposed.

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Protection advice began to appear in 1913, and in 1920, the British Roentgen Society issued a warning and recommendations (Clarke and Valentin, 2005). A study of its members covering the period 1897–1954 revealed that radiologists who entered the profession after 1920 had a *lower* cancer mortality and a *lower* mortality from all causes than comparable unexposed groups (Smith and Doll 1981). This was clearly satisfactory for radiation protection. Similarly, in 1934, the International Commission on Radiological Protection (ICRP) recommended a radiation limit: a "tolerance dose" of 0.2 R[†] per day, which implied the concept of a safe threshold. Multiplying this dose limit per day by the number of working days in a year (i.e., $0.2 \times 9.3 \times 5 \times 52$) corresponds to an annual radiation dose limit of about 500 mGy.

CHANGE FROM ORIGINAL RADIATION PROTECTION POLICY

After WWII, in response to concerns expressed by geneticists, the 1934 recommended limit was progressively lowered to 0.5 R per week in 1950. The explosion of two atomic bombs over Japan in 1945 had led to very strong political activities by many scientists against: 1) the ongoing development and testing of these weapons, 2) the expanding arms race, and 3) the growing potential for nuclear warfare. One of their strategies was to create and promote extreme social fear of low-level radiation from radioactive "fallout."

In June 1956, a Genetics Panel of the U.S. National Academy of Sciences (NAS) on Biological Effects of Atomic Radiation (BEAR) issued a report that misled the world community on cancer risk assessment (Calabrese 2013). In this report, the Panel recommended a linear no-threshold (LNT) dose–response policy for assessing risks to the genome from ionizing radiation (BEAR I, 1956), replacing the threshold dose–response model. A review of the process that led to this recommendation indicated scientific misconduct, as the research record was falsified to promote acceptance of the LNT policy. The Genetics Panel failed to provide any scientific assessment to support its recommendation and refused to do so when later challenged by

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 $^{^{\}dagger}$ A 1 R exposure to ordinary tissue results in an absorbed dose of about 9.3 mGy or 9.3 millijoule kg⁻¹ (Henriksen 2015).

other leading scientists (Calabrese 2015a and b). A further historical review of the detailed documentation and correspondence that was produced during the 1940s and 1950s by prominent radiation geneticists revealed how they successfully worked to build acceptance for the LNT model. Their actions in support of this policy revolution were ideologically driven and deliberately and deceptively misleading. Scientific records were artfully misrepresented. People and organizations in positions of public trust failed to perform the duties expected of them, significantly impacting environmental, occupational, and medical exposure standards and practices to the present time (Calabrese 2015c).

The NAS recommendation was quickly generalized to include somatic cells for cancer risk assessment and later was instrumental in the Environmental Protection Agency's adoption of linearity for carcinogen risk assessment. The recommendation was rapidly and widely promulgated, but the world regulators failed to examine thoroughly the basis of the LNT model before they accepted it (Calabrese 2015b). Thus, the current method of assessing excess cancer risk induced by radiation is based on ideology and the fraudulent actions of the NAS BEAR I Committee, Genetics Panel, and on the uncritical, unquestioning and blind-faith acceptance by regulatory agencies and the scientific community.

Accordingly, there is an international consensus to use the LNT model to predict the hypothetical excess cancer risk at any low dose or any low dose-rate by linearly extending to zero the measured excess risk in the high radiation range. The requirement to minimize this hypothetical cancer risk led to the radiation protection policy of ALARA (as low as reasonably achievable) and to the implementation of extreme precautionary emergency measures when a significant release of radioactive materials occurs. Since the regulators are focused on risk assessment, they may (and do) ignore any observations of beneficial health effects induced by low radiation exposures. Such errors of omission have led to the loss of very important medical benefits and costly barriers against affordable nuclear energy projects.

BENEFICIAL EFFECTS OF RADIATION

From the early 1900s, medical practitioners employed x rays and gamma rays, with doses in the range from about 50 to well above 1,000 mGy, to treat and very often cure a wide variety of illnesses, such as cancers, wounds, infections (gas gangrene, skin, sinus, inner ear, etc.), arthritis, inflammations, pneumonia, and asthma (Cuttler 2013, 2014, 2015; Calabrese et al., 2015). No significant increases in the incidence of cancer nor any other late adverse effects were apparent following these treatments. For example, nasal radium irradiation (NRI) was a standard medical practice from the 1920s until the 1960s to shrink swollen (infected) adenoids in children. At least 8,000 military personnel and

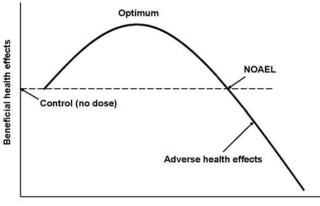
as many as 2.5 million children received NRI treatment. The typical gamma-radiation dose from each applicator was 20 Gy on contact and 2 Gy at 1 cm depth; the betaradiation dose was 0.7 Gy. U.S. Navy personnel received NRI to removed excess lymphoid tissue at the Eustachian tube openings that tend to prevent pressure equalization and cause middle ear problems. A National Cancer Institute fact sheet states that a clear link between NRI exposure and cancer risk (or any disease) has not been established (CDC 2014; CDC 1996; NCI 2003).

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A simple explanation for such beneficial effects is apparent from basic biology. Since the world changes constantly, all surviving organisms have adaptive protection systems that enable them to adapt to environmental changes over an exposure range that depends on their individual characteristics. The environment includes the natural background of ionizing radiation, which averages 2.4 mGy per year, but extends up to hundreds of milligray per year in high radiation background areas. When a large, short-term increase in radiation occurs, the immediately acting protection systems begin to prevent, repair, and remove damage, and restore cellular, tissue, and organism health. When a significant radiation increase occurs repeatedly or persists for a long time, then adaptive protection systems (more than 150 genes) are stimulated. They activate at different dose thresholds and can persist for days, weeks, and even years (Feinendegen et al. 2011, 2012). The protection systems act not only against the damage that was or is being induced by the radiation increase but also against the much more extensive damage or rate of damage that is occurring due to natural endogenous processes (Billen 1990) and the damages induced by exogenous causes, such as injuries, infections, and ingestion of chemicals. The overall response to a low radiation increase is a beneficial effect, an improvement in health that may include a reduction in the risk of cancer. When a high radiation increase occurs, protection systems are inhibited or damaged, resulting in overall harmful effects that may include an increase in the risk of cancer. Fig. 1 is the dose-response model that corresponds to this biological behaviour: low dose stimulation of protection and high dose inhibition. It shows the no observed adverse effects level (NOAEL), which is the threshold for adverse health effects, such as a reduction of expected lifetime or an excess cancer mortality compared to the control group.

A very important application of low-dose stimulation of adaptive protection is total- or half-body (TB/HB) lowdose irradiation (LDI) of cancer patients. Pollycove (2007) reviewed this treatment, which was carried out successfully at Harvard University in the mid-1970s. He strongly urged that clinical trials be carried out on breast, prostate, and colorectal cancer patients. In Japan in 1975, Sakamoto started fundamental studies on mice (Fig. 2), and he began clinical studies in the mid-1980s. More than 200 cancer patients

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Absorbed radiation dose

Fig. 1. Radiation hormesis dose–response model showing the no observed adverse effects level (NOAEL), which is the threshold for adverse effects, such as reduction of expected lifetime or excess cancer mortality.

were treated, mostly for non-Hodgkin's lymphoma. Good results were obtained, including many complete and longlasting recoveries. The combined treatment of TB/HB LDI and local high irradiation improves the cure rate by enhancing local tumor killing and by suppressing the distant metastases. However, LDI and combined therapy are not effective for advanced tumors, recurrent cases, or aged patients (Sakamoto 2004). Studies in China have demonstrated convincingly the effectiveness of cancer control by stimulation of immunity by low-dose radiation (Liu 2007). Studies in Canada confirm that a single, low, whole body dose of low LET radiation, given at a low dose, increases cancer latency and consequently reduces both spontaneous and radiation-induced cancer risk in both genetically normal and cancer-prone mice. This adaptive response lasted for the entire lifespan of all the animals that developed these

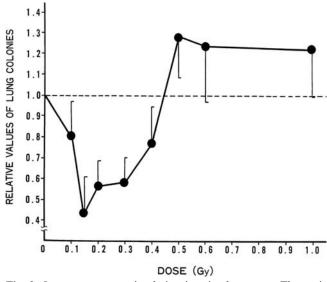


Fig. 2. Immune system stimulation in mice by x rays. The optimum dose is about 150 mGy; the NOAEL is about 500 mGy (Sakamoto 2004).

tumors and effectively restored a portion of the life that would have been lost due to the cancer in the absence of the low dose (Mitchel 2007a). Fig. 3 is a photo of Kiyohiko Sakamoto and a patient who received HB LDI therapy in Canada in 2011 as a *prophylaxis* against cancer recurrence following surgery to remove a tumor. Sakamoto prescribed an acute dose of 150 mGy twice each week for 5 wk—a total dose of 1.5 Gy. Since there were no symptomatic side effects, this "alternative treatment" is preferable to chemotherapy (Oakley 2015).

CHANGES TO RADIATION PROTECTION POLICY

Since low dose radiation reduces cancer risk and increases lifespan, the current ALARA policy for radiation protection is wrong and should be changed (Mitchel 2007b). Science-based regulations would remove the risk of losing the very important health benefits of using lowdose radiation in medical diagnostics and treatments. It would remove the fear of radon levels in homes and the social opposition against nuclear energy projects that are based on fear of radiation. Three important lessons should have been learned from the releases of radioactive materials from the Chernobyl and Fukushima reactors: 1) radiation levels in residential areas are increased to the levels in natural high background radiation areas; 2) each precautionary evacuation caused more than 1,000 avoidable deaths and more than 200,000 highly distressed victims due to their fears of cancers and harmful genetic effects (residents, caregivers and rescuers of tsunami victims); and 3) the exposures avoided by the evacuations would not have caused adverse health effects. Therefore, it is time to bring radiation protection policy back into line with the biological data and to inform the public about the real health effects of ionizing radiation.

There was a satisfactory radiation protection policy for the radiologists from about 1920 until it was changed



Fig. 3. Kiyohiko Sakamoto with a patient who was treated in Canada in 2011 with HB LDI as a prophylaxis against cancer recurrence.

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in 1956. The NAS-BEAR committee issued an unscientific recommendation to use the LNT hypothesis to assess the risks of genetic damage and excess cancer, which was followed by the international consensus of the regulators to do so. They should now examine the data that show beneficial health effects and change the radiation protection policy from ALARA to a policy of *as high as reasonably safe* (AHARS). Regulatory dose and dose-rate limits should be set just below the NOAELs. This would diminish the extreme social fear of any radiation exposure and lead to rational responses to nuclear events.

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