Current radiation protection limits: An urgent need for change

Appropriate revisions to radiation protection guidelines for medical and nuclear power applications will ultimately lead to major public health and economic benefits.

By Jerry M. Cuttler and William H. Hannum

Following the February 24 signing of Executive Order 13777, "Enforcing the Regulatory Reform Agenda," by President Donald Trump, Environmental Protection Agency Administrator E. Scott Pruitt issued a memorandum to EPA staff on March 24. This led to the EPA's April 11 announcement that it was seeking input on regulations that may be appropriate for repeal, replacement, or modification. On April 13, the EPA published a notice in the *Federal Register* that established Docket ID EPA-HQ-OA-2017-0190 to receive comments up until May 15. A total of 98,543 submissions were received as of May 20, with 31,378 results after filtering out those that did not meet the acceptance criteria. The authors provided comments on May 12 regarding the EPA's radiation protection regulations, as detailed in this article.

Current EPA regulations are based on the linear no-threshold (LNT) dose-response model. These regulations have long been considered to be conservative, and it is widely recognized that they are excessively restrictive. There is emerging evidence that the effects of low or even moderate levels of ionizing radiation are in fact beneficial. Researchers are now postulating that rather than being a simple cause of additional cell damage, the principal effect of low-level radiation is to stimulate the body's natural defense mechanisms—for instance, against cancer cells.

Many organisms receiving very high, but nonfatal, doses appear to have life expectancies as great as those receiving only normal background radiation. Higher-

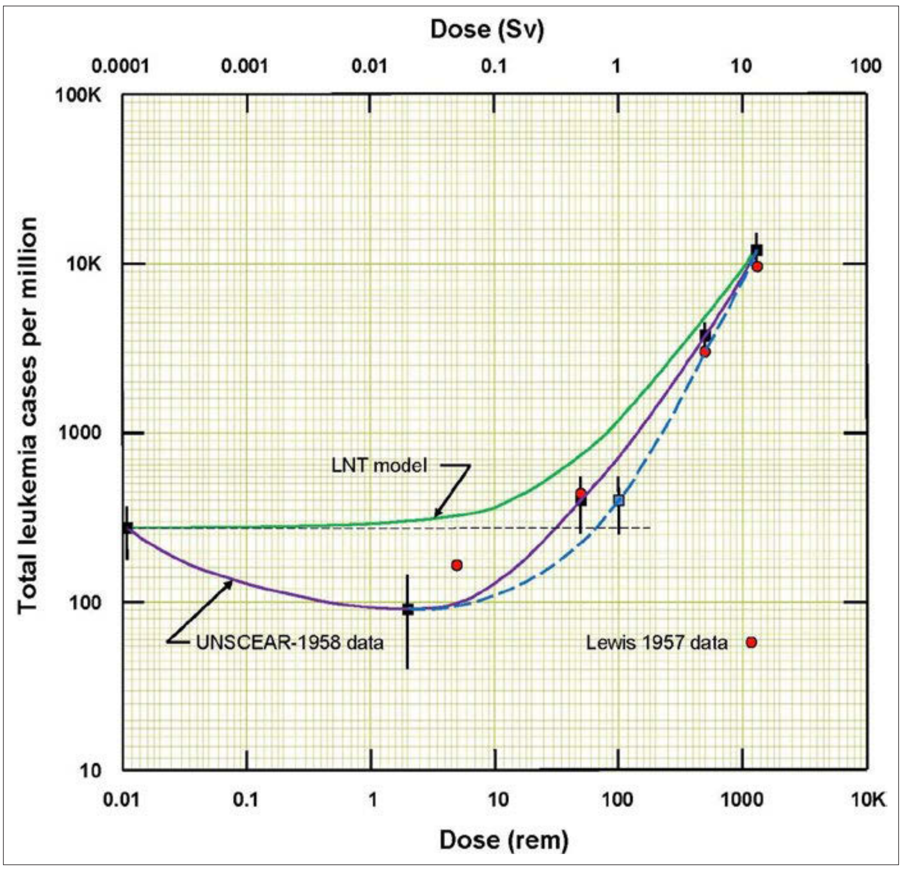

Fig. 1. Leukemia incidence from 1950 to 1957 among Hiroshima atomic bomb survivors.[1]

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than-normal background radiation does appear to increase longevity. Data from sources as diverse as Hiroshima survivors and beagle dog laboratory studies (conducted from the 1960s to the 1990s) are consistent in their conformance to a hormetic dose-response model, with surprisingly high thresholds for the transition between beneficial and harmful effects.

Confirmation and recognition of the potential benefits of low-level radiation will require a thorough review and revision of radiation protection guidelines for both medical and nuclear power applications. Appropriate revisions will lead to major public health and economic benefits.

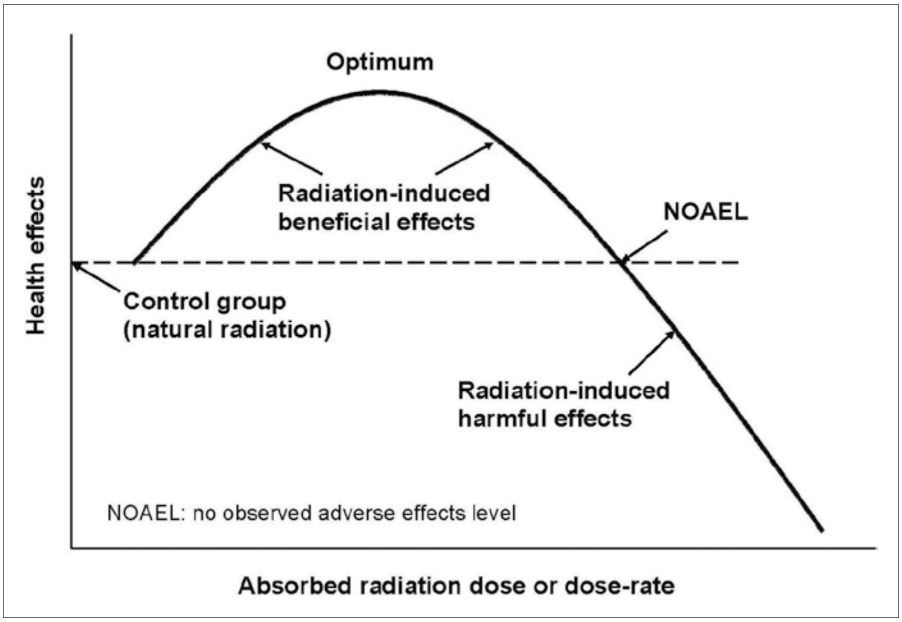

Fig. 2. Health effects caused by signals that are induced by radiation.

Background

Most of us are frightened by the thought of being exposed to nuclear radiation. Very high doses kill within days to weeks, and survivors of acute radiation illness show an increased risk of cancer. While most of the casualties of the atomic bombs that were used in Japan to end World War II died from the blast or the heat, many received very high doses of ionizing radiation. Some died from organ failure and others died from cancer that developed years later. Many emergency workers responded to the Chernobyl disaster, and 134 of them were heavily irradiated. Of these, 28 died within weeks, and 106 remained alive.

What about those who received high doses but survived? Since the most radiation-sensitive tissues are the blood-forming cells in bone marrow, leukemia is the cancer most likely to occur among the Japanese atomic bomb survivors, beginning at about five years after exposure. Figure 1 shows that there was no excess leukemia incidence for Hiroshima survivors when the dose was below about 500 mSv (50 rem). This suggests that the thresholds for initiating other types of cancer or other health risks are likely higher than 500 mSv.[1]

Of the 106 heavily irradiated Chernobyl emergency workers who remained alive, 22 died over the next 19 years, a mortality rate of 1.09 percent per year. This rate is lower than the average local mortality rate of about 1.4 percent in 2000. In 2001, this group's mortality structure was 26 percent cancer deaths among all mortality causes, which is not much different from the normal ratio in Central Europe.[2]

So how much radiation is too much? X-rays and nuclear radiation were discovered 120 years ago. Until the mid-1900s, before antibiotics and other modern remedies were discovered, medical practitioners used these radiations extensively to treat and cure patients who suffered from a wide variety of illnesses. In the early 1900s, geneticists began to study the incidence of radiation-induced mutations in the sex genes of fruit flies. Using very high doses at very high dose rates, they found that the mutation rate was roughly proportional to the radiation dose. By the 1920s, scientists determined a radiation level that is safe for all radiologists, a tolerance dose of 0.2 roentgen per day, or about 700 mSv per year. This limit was based on evidence of statistically recognizable adverse health effects, which occurred well above this level.[3]

While this forms a reasonable base for very large doses of radiation, whole-body exposures to a very high dose of radiation at a high dose-rate are extremely rare. The much more common situation is dealing with a long-term radiation level, as in coping with widespread contamination or other events that cause increases in background radiation. Because of the high natural incidence of cancers and the many factors that may affect cancer risk, it is impossible to establish a statistical relationship between low levels of radiation and an increased incidence of cancer.

In recent years, much has been learned about the body's responses to stress, including radiation stress, which causes cell and DNA damage.[4] Our bodies absorb several million energy deposition events—so-called hits—from gamma rays and about 15,000 particles every second. A third of these are from naturally radioactive atoms in our body and the rest are from outer space and natural materials in the environment. It has been that way throughout human existence. Our bodies have very powerful protection systems that prevent damage, repair damaged cells, and remove and replace unrepaired cells. These systems also cope with many internal and external toxins and diseases, enabling survival to an average age of about 70 years.[4]

By far, the greatest damage to our cells is caused by breathing air. We know that oxygen combines with food molecules to produce the energy that keeps us alive, but in the 1980s, scientists discovered that oxygen also attacks and damages cells. If not for our antioxidant production, each day every cell in our body would be damaged by a billion "free radical" molecules, mostly reactive oxygen species (ROS). Our body's natural damage prevention system lowers the potential damage rate to a million DNA alterations per cell per day. Most of these are harmless, but in about 1 of 10 cells, a double-strand break occurs per cell per day, on the basis of observed data. Our repair system lowers this damage rate further to about 1 mutation per cell per day. Most of the mutations are relatively harmless, but some change normal cells into cancer cells. To address this hazard, our body has further defense mechanisms, such as signal-induced cell death and the immune system, which recognizes cancer cells as foreign bodies and destroys them.[4,5,6]

So how does radiation fit into this picture? While the overall effects of high doses are well known, the detailed cell response mechanisms at both high and low doses are complicated and likely involve all levels of biological organization. Since about 75 percent of the human body is water, radiation-induced ROS is a very important effect. ROS and direct hits are a double-edged sword. They damage molecules, but some of the affected cells send signals to stimulate or inhibit genes.[4,5]

To obtain a perspective on the hazard, the rate of radiation-induced DNA damage should be compared with the rate of spontaneous ROS-induced DNA damage.

Continued

Natural radiation (1 mGy/year) induces on average about 0.01 DNA alterations per cell per day (1 percent are double-strand breaks), which is 100 million times less than the 1 million DNA alterations per cell per day that are calculated to be caused by breathing air. The radiation level would have to be quite high to induce the same rate of DNA damage as the spontaneous rate. This suggests that the observed health effects of a low dose or a low-level exposure are due primarily to cell signaling induced by radiation.[6]

The dose-response characteristic shown in Fig. 2 illustrates the nature of this signaling. As the radiation dose or dose-rate level increases above the ambient level, the stimulation of protection systems begins, and beneficial health effects start to be observed. As the dose or level increases further, the benefit increases until an optimum level is reached. Exposures beyond the optimum level reveal decreased benefit, which suggests that stimulation has decreased and inhibition has increased. At the level at which there is no observed adverse effect (NOAEL), the health effect is the same as for unexposed individuals. If the radiation dose or dose-rate exceeds the NOAEL, the inhibition of protection systems exceeds their stimulation, and health detriment is observed. The NOAEL point is the dose or dose-rate threshold for the onset of harmful effects.[7]

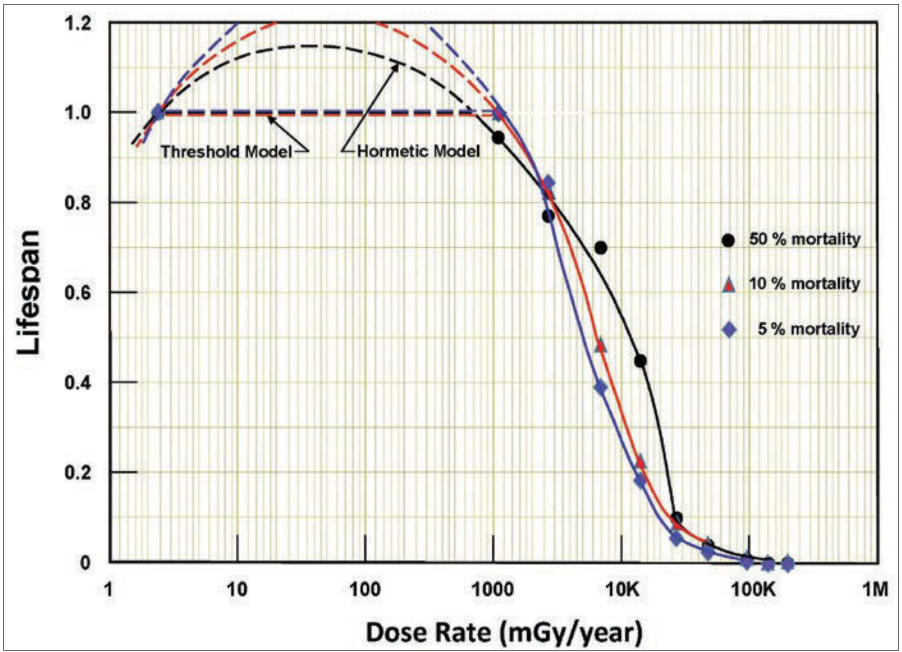

Fig. 3. Lifespans of groups of dogs at different gamma radiation dose rates.[5]

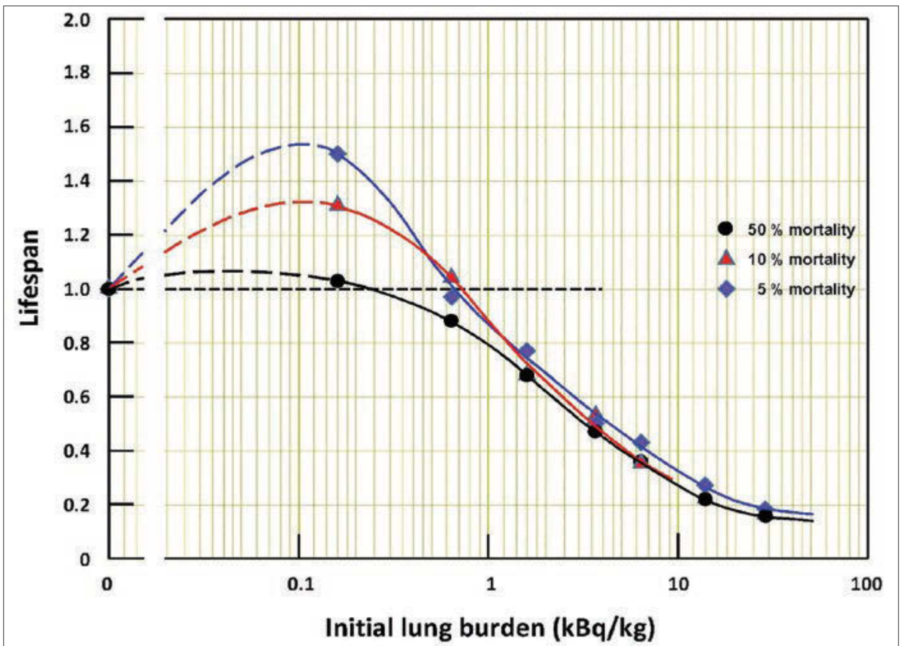

Fig. 4. Lifespans of groups of dogs at different initial lung burdens of inhaled plutonium aerosols.[5]

Many studies have been carried out by the U.S. Department of Energy and its predecessor agencies since the 1950s to determine the effects of radiation on humans. Beagle dogs are assumed to model humans well and have been the preferred choice for many studies. A recent analysis of data measured in two of these early studies sought to assess the effect of continuous radiation exposure on longevity for radiation-sensitive and for average individuals.[5]

Figure 3 presents evidence of a dose-rate threshold (NOAEL) at about 700 mGy per year for gamma radiation–induced reduction of lifespan in dogs. Figure 4 shows evidence of a threshold (NOAEL) for inhaled plutonium particulates. Figures 3 and 4 suggest an increased lifespan when the radiation level is below the threshold for harm, and also demonstrate that short-lived dogs are more radiation sensitive than average dogs. Short-lived dogs benefit more than average dogs when the radiation level is below the threshold and suffer more when the level is above the threshold. This evidence also implies that even sensitive individuals do not require special protection against low-level radiation.[5] The acute exposure data of the Hiroshima survivors shown in Fig. 1 are also consistent with the dose-response characteristic shown in Fig. 2, suggesting that the threshold (NOAEL) for a short-duration radiation dose to induce leukemia is about 500 mSv.[1]

Current regulations

After World War II, radiation protection became politicized, as many scientists tried to stop further testing and prevent the development of advanced nuclear weapons. Radiation exposure has never been shown to cause hereditary effects in human populations, but X-rays and nuclear radiations are known to cause mutations in cells, which can contribute to the risk of cancer. In 1956, without documented evidence, the U.S. National Academy of Sciences issued a report recommending that the risk of radiation-induced genetic mutations be assessed using an LNT dose-response model.[8] That is, the inferred health effect would be based on an integration of dose over time and over population groups, with no credit given for biological protection mechanisms. Government regulators worldwide accepted this advice,[8] causing broad public fear of low-level radiation.

The International Commission on Radiological Protection (ICRP) rejected the concept of a safe threshold dose limit and instead adopted a concept intended to keep cancer and genetic risk small compared with other hazards in life. According to the ICRP, "Since no radiation level higher than natural background can be regarded as absolutely safe, the problem is to choose a practical level that, in the light of present knowledge, involves negligible risk."[9] Cancers that exceed the number expected to occur naturally are attributed to the "stochastic effects" of radiation. The probability of occurrence, not the severity, was assumed to be proportional to the size of the dose. The ICRP employs the LNT model to calculate the risk of "health effects," which means that there is assumed to be a risk of excess cancer deaths in a population that receives a low radiation exposure, no matter how small. The risk of cancer is assumed to increase linearly with the cumulative radiation dose received (or number of cells damaged), regardless of the dose rate. Observations of radiation-induced beneficial effects (a lower cancer incidence) are disregarded. The ICRP does not accept the fitting of data with the hormetic dose-response model to predict positive health effects.

The international consensus to use this method of risk assessment continues to the present time. Since 1956, all medical personnel have been taught this primitive dose-response model and the idea that every exposure to ionizing radiation increases the risk of cancer, cumulatively. Radiation oncologists employ high radiation doses locally to destroy cancerous tumors, shielding healthy tissue. Radiologists apply low-dose radiation only for medical imaging, not treatment, and they justify and optimize all such exposures to minimize the hypothetical risk of cancer.[10]

High cost of regulations

Are there reasons to reevaluate these standards? The use of the LNT model is said to be conservative, but it leads to costly precautionary emergency measures that cause enormous suffering with no reduction in actual health risk. In response to concerns about hypothetical cancer risks, the regulatory bodies have set exposure standards that are based on the principle of dose minimization.[11] These standards are a barrier to many applications of low doses of radiation for medical diagnostics and treatments.[12] Tight regulatory restrictions and social fears obstruct the progress of projects to construct nuclear power plants that would generate reliable and secure electricity.[10]

The scientific advances in radiobiology over the past 35 years have been enormous. The detailed cell response mechanisms are complicated and involve all levels of biological organization.[4] Nevertheless, there is a good understanding of the biology that underlies the dose-response relationship shown in Fig. 2. Unfortunately, nearly all physicians today are still being taught the recommendation of 1956, thereby perpetuating the false cancer scare. The scientific evidence, shown in Figs. 1, 3, and 4, and the scientific misconduct that has occurred are being ignored.[8] This information is not being adequately communicated to the public, so the extreme social fear of exposure to a low level of (human-made) radiation continues.

The body's immune system generally detects and destroys cancer cells to prevent the development and spread of cancer. A weakened or impaired immune system is usually a precondition for cancer mortality. The DNA damage rate caused by low-level radiation has been shown to be negligible when compared with the spontaneous rate of damage that is managed by the protection systems (more than 150 genes), which include the immune system.[6]

Low doses of radiation stimulate the protection systems, enabling organisms to exceed their life expectancies. Studies have shown that low doses or low levels of radiation increase lifespan in animals and humans.[5,10] People living in high natural background regions tend to have greater, not shortened longevity. The 120 years of medical experience in the use of low radiation doses for diagnostic imaging and therapies, such as nasopharyngeal radium irradiation, have shown no significant risk of cancer or any other disease.[10] Whole-body or half-body treatments with low doses of radiation have been employed to cure hundreds of cancer patients.[10,12] It is not rational to set the safe limit at 1 mSv per year and enforce a radiation protection policy of "as low as reasonably achievable" (ALARA) when the natural background radiation level extends to 260 mSv per year in Ramsar, Iran, a city of about 35,000 people.

Overly conservative regulatory limits require hugely expensive measures to prevent even a minimal release of any radioactive material or an exposure to low-level radiation during normal power plant operation and from potential accidents of every beneficial application of X-rays, nuclear materials, and nuclear power. They preclude or restrict the constructive use of radiation in medicine.[10,12]

Among the most egregious consequences of the precautionary emergency measures following the 2011 Fukushima Daiichi nuclear accident in Japan are the effects on the health of the residents (about 1,500 premature deaths among the evacuees) and the impact of the radiation scare on the economy. It has become obvious that society is paying a very high price because of public fear of low-level radiation. The same can be said about the 1986 Chernobyl accident in Ukraine. The cost of the cleanup activities could have been much lower. Accident mitigation was very costly when vast areas around the Fukushima and Chernobyl power plants were deemed unfit for residency or farming.

There are many nuclear sites from the weapons program that need remediation to isolate from the environment materials that are unduly radioactive. The application of overly restrictive requirements is increasing the costs for these actions astronomically, and is thus hampering the effective cleanup of actual hazards and nuclear wastes.

Urgent need for change

The science shows that the "no-threshold" basis for radiation regulation is wrong.[11] While there is need for a constructive debate to establish safe limits, rational thresholds should be adopted now for dose and dose rate, based on current knowledge, and all radiation protection standards should be changed to reflect such thresholds.[10]

Since there is credible evidence of significant stimulatory benefits from exposures to different types of ionizing radiation, in a defined range of dose or dose rate, studies to quantify and optimize these effects should be encouraged.[12]

Responsible regulations, based on scientific medical evidence, would restore public confidence in the safety of nuclear energy and the efficacy of medical applications of low doses of radiation and would avoid the needless expenditure of enormous amounts of money.[13]

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