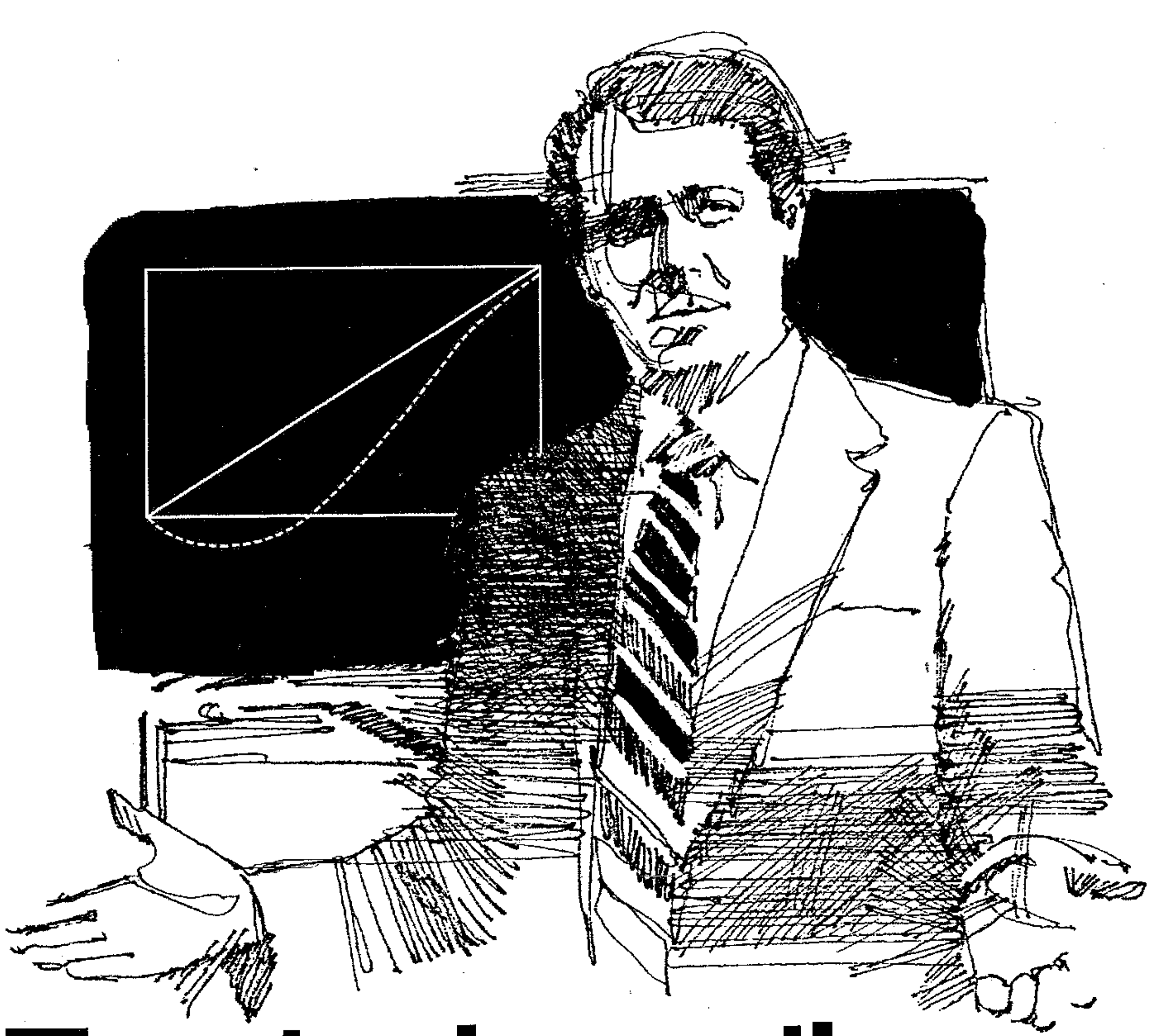

Time to change the linear hypothesis?

Are there sufficient data to change the assumption that there is a linear relationship without threshold between dose and effect?

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Radioactive material and ionizing radiation are useful tools for a variety of professions. Measuring the dose of ionizing radiation is a critical part of radiation protection and waste disposal programs. These activities are aimed at keeping doses to workers and the public within regulatory requirements.

The regulatory requirements are generally based on recommendations of the International Commission on Radiation Protection (ICRP) and the National Committee on Radiation Protection and Measurements (NCRP). EPA, the Nuclear Regulatory Commission (NRC), and the Department of Energy (DOE) are the three federal agencies that promulgate, in response to legislation signed by the president, most of the federal regulatory requirements for radiation protection and radioactive material waste disposal. Those requirements all contain dose limits and the additional mandate to maintain doses as low as reasonably achievable (ALARA) below those limits. The limits and the ALARA requirement are based on a

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specific model that relates dose to health effect. The health effect of most current concern is cancer.

The problem

Compliance with regulatory dose limits and the ALARA requirement currently costs all American taxpayers and certain electric rate payers billions of dollars. Those costs in large part are the result of the model used to relate dose to effects. But the model, in my opinion, is wrong for low-radiation doses. As a result millions, and perhaps billions, of dollars are wasted performing radiation protection and waste disposal activities that have no measurable benefit.

What is the linear hypothesis?

The linear hypothesis is the model on which the ionizing radiation dose-versus-effect curve is based for purposes of setting radiation protection standards.

Between 1896 and 1928, some deleterious effects of high doses of ionizing radiation were clearly observed. A concerned international group who worked with radiation and radioactive materials met at the end of that period to establish standards for radiation protection for radiation workers. They recommended some values for maximum permissible doses but, because they couldn't establish a threshold for radiation effects, they said, "The most conservative approach would be to assume that there is no threshold and no recovery, in which case, even low accumulated doses would induce leukemia in some susceptible individuals, and the incidence might be proportional to the accumulated dose" (*1*).

The ICRP turned that statement into what we now call the linear no-threshold hypothesis (LNTH) and stated it as, "One such basic assumption...is that... there is...a linear relationship without threshold between dose and the probability of an effect" (*2*). The NCRP stated the hypothesis as, "In the interest of estimating effects in humans conservatively, it is not unreasonable to follow the *assumption* of a linear relationship between dose and effect in the low-dose regions for which direct observational data are not available" (*3*). The LNTH is now applied, not only to radiation workers, but also to the public.

When the atomic bombs were dropped on Hiroshima and Nagasaki, Japan, many thousands of survivors were exposed to high doses of radiation. The United States and Japan established a group of scientists to determine the doses to those people and to follow them medically to determine the health effects of those doses. The data from that work, gathered from 1946 to the present, are the major determinants of the current radiation protection recommendations of the ICRP and the NCRP. In the linear hypothesis, those high-dose data are used to establish the upper part of the line. The line is assumed to pass through the origin. According to the linear hypothesis, there may be no dose, no matter how small, for which there is no effect. Therefore, the model is often called the LNTH.

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Data from other high exposures to various populations have also been used to establish the upper part of the LNTH line. However, in the early days of the ICRP and the NCRP, there were few data points in the low-dose region of zero to a few tens of rem upon which to base the lower part of the line. (Rem is a unit of radiation dose; it is expressed in terms of energy absorbed in matter per unit mass. Humans receive about 0.3 rem per year from natural background radiation.) Accordingly from the 1950s through the 1970s, it was not unreasonable—in light of the lack of knowledge about low-dose effects—to use LNTH as the basis for radiation protection standards. However, LNTH has been with us unchanged for more than 40 years.

The current situation

Data now show that low doses of radiation are not harmful (*4–16*). Some scientists warn that a single agent (e.g., radiation) that is carcinogenic for one type of cancer also can reduce cancer incidence for other types of cancer. Thus regulators should be cautious in proscribing suspected carcinogens lest they do harm by such action (*17, 18*). Some data even demonstrate that low doses are beneficial (e.g., exhibit a hormetic effect) (*19, 20*). Luckey, Bowers, and Cleveland question whether ignoring the radiation hormetic effect constitutes "...a very serious error in modern biomedical science..." (*21*). Even the courts have said, "As the name itself notes, this [linear hypothesis] is not proven fact. It is only a hypothesis" (*22*). However, neither the ICRP nor the NCRP is yet willing to consider such information sufficient to change LNTH. Formal actions have not yet been taken to request the federal agencies to revise their regulations.

Evidence that LNTH is not valid

The ICRP and NCRP admit that LNTH is only that, a hypothesis. The ICRP has said, "The commission is aware that the assumptions of no-threshold and of complete additivity of all doses may be incorrect, ..." (*23*). The NCRP has said, "Important elements in the [LNTH] approach that need to be recognized include:... (2) Uncertainty in the extrapolation of risks from exposures at high dose, ...to exposures at low dose and low-dose rate...since, at very low doses, the possibility that there is no risk cannot be excluded. This uncertainly is...most likely the predominant uncertainty in the estimate of risk at low doses" (*24*).

In 1973, N. A. Frigerio and collegues at the Argonne National Laboratory concluded: "Observation of the actual populations at risk (from radiation effects of low doses) shows not only no increment, but an actual decrement, so that these [risk] predictions are left quite without observational support" (*5*). B. L. Cohen has demonstrated an inverse relationship between radon concentrations in homes and lung cancer, in direct opposition to the predictions of LNTH (*25, 26*). R. D. Evans demonstrated a threshold form bone sarcoma from radium ingestion in direct contradiction of LNTH (*27–29*).

The American Nuclear Society has presented several sessions on LNTH at which every speaker presented evidence against or showed the unintended result of LNTH (*30–32*). Jim Muckerheide has summarized a large body of data demonstrating the lack of validity of LNTH (*33*).

In 1985, the Health Physics Society (HPS), a professional organization dedicated to the development, dissemination, and application of the scientific knowledge of, and the practical means for, radiation protection, sponsored an entire meeting on radiation hormesis (the beneficial effects of radiation) (*34*). The existence of radiation hormesis directly contradicts the predictions of LNTH that low doses are harmful. The United Nations Scientific Committee on the Effects of Atomic Radiation admits to the existence of hormesis in its latest report (*35*).

Perhaps the clearest statement against LNTH is that of Victor Bond, a member of the NCRP, who wrote, "The evidence presented here suggests that the radiation limits-setting bodies should seriously consider abandoning, overtly and completely, the linear, nonthreshold hypothesis as a scientifically valid premise and the core of radiation protection philosophy, principles, policies, and practice" (*36*).

Current activities

The HPS Scientific and Public Issues Committee has issued a position paper on LNTH for use in communication with the public. That paper expresses the opinion that radiation risks below 10 rem should not be made because the data on which such risks would be based do not exist.

The NCRP has established a committee to reexamine LNTH to see if it remains viable as the basis for radiation protection standards. That committee is chaired by Arthur Upton of the Brookhaven National Laboratory, a long-time NCRP member, who has stated in the past, "We cannot prove, and we no longer assume, that there is a threshold [for low level radiation effects]. This was because there was no proof that the cancer risk from radiation was greater than zero...Because we know radiation can do harm, and because we have no confidence in the existence of a threshold, we must do everything possible to minimize the unnecessary radiation exposure..." (*37*).

The current paradigm

A result of LNTH, unintended by the ICRP or the NCRP, is that it has been corrupted. A paraphrase of the original LNTH is, "a little radiation may produce harm." That paraphrase has been corrupted into "low doses of radiation will hurt you." The assumption has become a statement of fact for millions of people.

How did this occur? The regulatory agencies, particularly EPA, did not and do not emphasize that their estimates of radiation effects are only that, estimates, and do not necessarily represent reality. EPA radiation guidance says, "It is assumed that there is no completely risk-free level of exposure" (*38*); but, after it says that once, it omits the "assumed" and states calculated deaths as though they were real. The public reads right over the first "assumed" and sees only the deaths. Furthermore, federal regulatory agencies—primarily NRC, DOE, and EPA—have used LNTH as the basis for their regulations and guidance.

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So federal agencies are guilty of not ensuring that the public correctly interprets what the agency has written.

The antinuclear people have used, and continue to use, the corruption for all it is worth to frighten the public about the effects of radiation.

Scientists and the nuclear industry itself have not effectively countered the corruption whenever it was stated.

The public has accepted uncritically the antinuclear people's version.

Congress, without thoroughly researching the basis for the ICRP and the NCRP recommendations, has made conflicting and ambiguous laws that incorporate the corruption.

The media have accepted uncritically the antinuclear people's untruth.

How have the various players interacted to create the corruption? The antinuclear people have been the most active; they feed the media and the regulators biased information to further their agenda. The nuclear industry has not done enough to counter that information. Congress has not held the kind of hearings it did in the 1950s and 1960s to get the facts about things nuclear. Scientists have adopted the most conservative model and have not done enough to ensure that the public knows it is only a model and the real radiation effects may be zero or may even be beneficial. The media are just as afraid of radiation as the public and use fear to sell their products. The public as a rule accepts the media's information without question. So, all players interact with one another with a very detrimental result.

The result has been

- very high cost of radiation protection,
- no new nuclear power plants in the United States,
- no fuel reprocessing,
- no research on new reactor types,
- no mixed oxide fuel use,
- no breeder reactors,
- no new radioactive material waste disposal sites, and
- decreasing use of radioactive material in research.

The LNTH is the major reason that the result is observed.

Cost of LNTH

The significant question that must be asked is: "Can the United States maintain global competitiveness when spending billions of dollars, argueably for no benefit?"

LNTH results in high costs of radiation protection, decontamination, decommissioning, and waste disposal. Some states and counties have passed laws that prohibit placing any radioactive material in their local landfills. Therefore, all waste from a nuclear facility must be sent to an authorized radioactive waste disposal site at significant cost. If it were perceived that a little radiation may be good for you (or at least is not harmful), those laws would not be promulgated, and the waste disposal cost would be significantly reduced.

Gail de Planque, former NRC commissioner, provided an excellent analysis of the costs for environmental measurements for cesium-137 in soil for a decommissioned site as a function of the annual dose. Her analysis showed that, if the dose limit were 0.3 mrem per year, the sampling cost would be $500 per measurement. If the dose limit were 30 mrem per year, the sampling cost would be $50 per measurement. That factor of 10 adds up to a large amount of money if many measurements are needed at a site (*39*). The major actual cleanup costs increase significantly as the dose limit decreases. Those costs escalate exponentially as the limit goes down.

Finally there are the emotional and dollar costs to workers and the public when irrational fear of low doses causes lawsuits and delays in establishing new radioactive waste disposal sites.

I conclude that LNTH and its corruption are the direct cause of public fear of low levels of radiation. That fear is translated by regulators and regulatory agencies into very stringent and unnecessary dose limits and ALARA evaluations. The limits and evaluations (costly in themselves) result in requirements for radiation protection and actions to clean up contaminated sites at great expense.

Replacing LNTH

I suggest the following to replace LNTH:

Establish standards for human and environmental health and safety, such as 5 rem per year. Low-level radiation detection instrument manufacturers, photographic film makers, computer chip manufacturers, low-level counting laboratories, research laboratories, and others would not want contamination by radioactive material in their facilities. So, practical, site-specific standards for protection of items and premises might be more stringent than the safety standards. The public would recognize that even though the latter standards were more stringent, the stringency is appropriate, much like "clean rooms" in electronic manufacturing.

An ancillary benefit of the demise of the linear hypothesis is the concomitant demise of the ALARA concept below the annual limit. Also, the question of collective dose at low doses goes away. Safety is not diminished nor compromised by the loss of those two concepts, but much cost is saved.

The evidence suggests that the radiation limits-setting bodies should seriously consider abandoning the linear, nonthreshold hypothesis as a scientifically valid premise.

In closing

Adhering to the scientific method requires a scientist to accept a hypothesis or theory until data demonstrate it is not true. W. C. Röntgen said, "It is almost always possible to compare the results of thought processes with reality to provide the experimental scientist with the proof he needs. If the result does not agree with reality, the former is necessarily incorrect, even if the speculation which led to the result was ever so ingenious or fanciful" (*40*). Chiao said, "As a scientist, you must hold all theories provisionally and be open to new data showing that a theory is wrong" (*41*).

Data demonstrate that LNTH is wrong. LNTH should no longer be the basis for radiation protection standards.

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