# **Dose-Response: An International Journal**

Volume 10 Issue 2 Special Issue on the Role of Linear and Nonlinera Dose-Response Models in Public Decision-Making

Article 6

# 6-2012

# THE LNT DEBATE IN RADIATION PROTECTION: SCIENCE VS. POLICY

Kenneth L Mossman Arizona State University

Follow this and additional works at: https://scholarworks.umass.edu/dose response

# **Recommended** Citation

Mossman, Kenneth L (2012) "THE LNT DEBATE IN RADIATION PROTECTION: SCIENCE VS. POLICY," *Dose-Response: An International Journal*: Vol. 10 : Iss. 2, Article 6. Available at: https://scholarworks.umass.edu/dose\_response/vol10/iss2/6

This Article is brought to you for free and open access by ScholarWorks@UMass Amherst. It has been accepted for inclusion in Dose-Response: An International Journal by an authorized editor of ScholarWorks@UMass Amherst. For more information, please contact scholarworks@library.umass.edu.

Dose-Response, 10:190–202, 2012 Formerly Nonlinearity in Biology, Toxicology, and Medicine Copyright © 2012 University of Massachusetts ISSN: 1559-3258 DOI: 10.2203/dose-response.11-017.Mossman

# InternationalDose-ResponseSociety

## THE LNT DEBATE IN RADIATION PROTECTION: SCIENCE VS. POLICY

Kenneth L. Mossman D Arizona State University

□ There is considerable interest in revisiting LNT theory as the basis for the system of radiation protection in the US and worldwide. Arguing the scientific merits of policy options is not likely to be fruitful because the science is not robust enough to support one theory to the exclusion of others. Current science cannot determine the existence of a dose threshold, a key piece to resolving the matter scientifically. The nature of the scientific evidence is such that risk assessment at small effective doses (defined as <100 mSv) is highly uncertain, and several policy alternatives, including threshold and non-linear dose-response functions, are scientifically defensible. This paper argues for an alternative approach by looking at the LNT debate as a policy question and analyzes the problem from a social and economic perspective. In other words, risk assessment and a strictly scientific perspective are insufficiently broad enough to resolve the issue completely. A wider perspective encompassing social and economic impacts in a risk management context is necessary, but moving the debate to the policy and risk management arena necessarily marginalizes the role of scientists.

Key words: radiation protection, policy, science, LNT, ALARA

## **INTRODUCTION**

Protection of workers and the public from ionizing radiation exposure is based on the assumption that cancer incidence or mortality risk is a linear function of radiation dose, and any dose of radiation, no matter how small, may cause cancer. The linear no-threshold (LNT) theory serves as the philosophical and practical foundation for risk assessment and management of exposures in the environment and workplace. Standard-setting organizations such as the U.S. Nuclear Regulatory Commission (U.S. NRC) and the Environmental Protection Agency (EPA) rely on independent authoritative bodies to provide analyses and evaluations of scientific evidence in support of their standard setting policies. The U.S. NRC and EPA rely on the National Council on Radiation Protection and Measurements (NCRP) and the National Academies for such advice. In a 2001 report NCRP concluded the LNT theory is the most appropriate theory for radiological risk assessment because the available scientific data did not overwhelmingly support an alternative theory. The National Academies in its 2005 BEIR VII report drew similar conclusions. EPA and U.S. NRC continue to use LNT theory in risk assess-

Address correspondence to Kenneth L. Mossman, School of Life Sciences, Arizona State University, Tempe, AZ 85287-450; Phone: 480.965.0584; Fax: 480.965.6899; Email: ken.mossman@asu.edu

ment in accordance with the position that other theories are not more plausible (National Council on Radiation Protection and Measurements 2001; National Research Council 2005).

LNT theory provides a conservative estimate of cancer risk at low doses, and it is easily communicated and understood by policymakers and the public. But the notion that any dose may be harmful and that no dose is safe leads to a regulatory framework and philosophy characterized by public fear and increasing regulatory compliance costs (Mossman 2006).

There is now considerable interest in revisiting LNT theory as a scientific basis for radiation protection practice. In 1989 Sagan suggested a reexamination of the scientific evidence in support of LNT because the evidence for hormesis (i.e., biphasic) and other nonlinear dose-response functions appeared to be considerable and deserved more serious attention (Sagan 1989). The nature of the scientific evidence is such that risk assessment at small effective doses (defined as <100 mSv) is highly uncertain, and several policy alternatives, including non-linear dose-response functions, are scientifically defensible. Estimates of cancer incidence and mortality due to small effective doses depend on the choice of predictive theory. In spite of significant gains in our understanding of the processes of carcinogenesis, there remains no adequate model of carcinogenesis that permits derivation of a predictive theory from first principles.

This paper argues for an alternative path to resolving the LNT policy conundrum. Continuing the debate on a scientific basis is not likely to be fruitful because the science is not robust enough to support one theory to the exclusion of others. Current science cannot determine the existence of a dose threshold, a key piece to resolving the matter scientifically (National Research Council 2005, Puskin 2009). An alternative approach is to look at the LNT debate as a policy question and analyze the problem from a social and economic perspective. In other words, risk assessment is insufficiently broad enough to resolve the issue completely. A wider perspective encompassing social and economic impacts is necessary, but moving the debate to the policy and risk management arena necessarily marginalizes the role of scientists.

The argument for a policy solution is based on the following themes that are discussed more fully in the remainder of the paper:

Science and policy address different questions. Science cannot address all policy-relevant questions.

Defensible science alone is not sufficient to establish policy (but indefensible science is sufficient to reject policy).

Science does not usually drive policy

The LNT debate is being played out entirely in the science arena with the view that science should drive policy choices. There has been little discussion of the economic, political and social dimensions of policy making. Individuals and groups of scientists tend to promote particular policy choices based on available scientific evidence. Some are proponents of linearity; others believe a threshold or nonlinearity (including a biphasic dose-response) is more scientifically-defensible. The controversy has been ongoing for years and raises questions of the role of science and the scientific community in policy deliberations. Battles waged only in the scientific arena will not resolve fully the policy question because scientific data and their associated uncertainties are only part of the problem. The implications of a conservative, LNT approach is a higher degree of safety but costs of managing small doses can be enormously expensive (Breyer 1993). A less conservative policy would reduce regulatory costs considerably (Mossman 2009).

Risk assessment (science) and risk management (policy) ask different questions (Table 1). Risk assessment focuses on identifying the hazardous agent and the at-risk populations, the likely exposures, and the consequences of exposure (including public health and environmental effects, severity, magnitude, variability and uncertainties). Risk assessment information is provided to decision-makers and risk managers concerned with feasibility of risk reduction, and costs and benefits of interventions including economic, social, political and cultural impacts. The failure to uncouple risk assessment from risk management has made it difficult to resolve the LNT question completely. Assessment and management of risks should be clearly separated processes. Risk assessment is a purely scientific and technical effort, and terminates with a quantification of the risk. It is the role of the risk manager to manage the risk that the risk assessor has quantified. Risk management involves decision making and the taking of action. Thus, the matter of preferences, values, policies and decision making belongs within the framework of risk management, not risk assessment (Mossman 2009). The National Research Council has been a strong proponent of the separation of policy/value judgments that are cornerstones of risk management from the scientific and technical aspects of risk assessment (National Research Council 1983, 1994, 2007).

Science ( Risk Assessment)	Policy (Risk Management)	
1. What can go wrong?	1. What are the risks posed by human activities and	
	natural phenomena on society and the environment?	
2. How likely is it to happen?	2. Are these risks acceptable?	
3. What are the consequences?	3. Can these risks be reduced?	
-	4. On what basis should we choose among these options?	
	5. How confident are we about our analyses?	

**TABLE 1.** Science and policy focus on different questions

The fundamental issue is the failure to recognize the limits of science in decision-making. The process of making sound decisions is based on a careful consideration of all scientific and non-scientific dimensions of the problem including economics, cultural and social issues, politics and values (Pielke 2007). Many of the issues that lie at the interface between science and policy involve questions that can be stated in scientific terms but are in principle beyond the proficiency of science to answer. Weinberg coined the word "trans-scientific" to describe these types of problems. He argues that for problems attended by large uncertainty or having strong political overtones such as health risks of low doses of ionizing radiation adequate solutions cannot be supplied by science alone (Weinberg 1972).

# A SCIENCE (RISK ASSESSMENT) PERSPECTIVE

In an idealistic world scientific evidence in support of a particular theory is unequivocal and a path forward to establishing policy is clear. The scientific evidence is robust enough to support one policy to the exclusion of alternative policy choices. Unfortunately in the real world this is not the case. Scientific evidence is not unequivocal and several policy options are scientifically defensible. The way forward is not clear cut. Uncertainty in the science makes policy choices difficult (Pielke 2007).

Radiogenic risk assessment is a complex process because risk information cannot be measured directly. Direct observations of radiogenic health effects are observed at doses 2-3 orders of magnitude higher that typically encountered in environmental and occupational settings. To predict the magnitude of health risks necessitates the use of predictive theories involving questionable assumptions. For example the assumption of no repair of biological injury in LNT theory is known to be untenable (Mossman 2006). Dose and dose-rate effectiveness factors (DDREF) are used to adjust LNT-derived risk coefficients to account for biological repair. The extent of repair is an important determinant of risk. DDREF values are not known very well and values close to unity are typically used to estimate risk conservatively. The usefulness of risk assessment for decision making is limited by the extent of uncertainty in the analysis.

Estimation of low-dose radiation risk is associated with uncertainties in measurement of risks and uncertainty inherent to modeling complex biological systems. There is little epidemiological evidence to support statistically significant radiogenic risks below 100 mSv (National Research Council 2005, Mossman 2006, Puskin 2009). The major source of risk data used in radiation protection is the Japanese Life Span Study (LSS). The LSS has been going on for more than 50 years involving about 85,000 Japanese survivors of the atomic bombings of Hiroshima and Nagasaki in 1945 (Preston *et al.* 2003). Although cancer risks are derived primarily from those survivors exposed to high doses (>500 mSv) in reality the LSS is really a low dose study. Over 85% of the subjects (including controls)

were exposed to doses below 200 mSv. The number of excess cancers attributable to radiation exposure in the <200 mSv group (the difference in cancer deaths between exposed and unexposed groups) is within random statistical error. Only at higher doses are the excess cancer deaths large enough relative to the number of subjects exposed to result in statistically significant risk. The fact that risks cannot be detected at statistically significant levels at doses below 200 mSv does not discount the value of the low dose data (Mossman 2006).

The LSS makes a clear statement that at low doses (<200 mSv) radiogenic cancer risk cannot be measured. It is unclear from the data whether the risk is zero or too small to be measured reliably. The inability to measure risk cannot be used as evidence to support the existence of a threshold. To do so would require clear evidence of absence of risk.

If no one in the LSS was exposed to doses above 200 mSv there would be little evidence to support cancer as the major health effect of exposure at low doses. It is interesting to speculate how risk estimates, regulations and the framework for radiation protection might have evolved without the key epidemiological data above 200 mSy. It is safe to conclude that cancer would have ultimately been identified as an important health outcome at low doses because of experimental animal studies and also from studies of radiotherapy patients. Although radiotherapy involves very high doses to localized diseased areas, tissues outside of the treatment volume get a small measurable dose that increases cancer risk. Radiotherapy doses depend on tumor site and are typically in the range of 40 Gy to 70 Gy<sup>1</sup>. Normal tissues surrounding the tumor may receive scatter doses about 1% of the total tumor dose or about 0.5 Gy. This scattered dose is high enough to increase risks of second cancers particularly in children and young adults. Risks of second cancers have been used to corroborate the risk estimates derived from the LSS (Hall and Giaccia 2006).

The lack of power in epidemiological studies to detect significant radiogenic risks at low doses is due to the low signal (the radiogenic cancer risk) and high noise (high natural or spontaneous cancer risk) characteristic of human populations. Power is the probability of detecting an effect when the effect is present, The ratio of the "signal" to the "noise" determines the size of the population needed to detect risk at a given radiation dose. Huge populations are needed because the signal to noise ratio is very low (only about 2% at 100 mSv). A population of about 1 billion persons (roughly one-sixth of the world's population) would be required to detect a cancer risk from natural background radiation exposure (assumed to be about 1 mSv per year excluding contributions from radon) if such a risk actually existed. A population of about 10 million

<sup>&</sup>lt;sup>1</sup>The gray (Gy) is the unit of absorbed dose. For x and gamma rays, the Gy and Sv are numerically equivalent: 1 Gy= 1 Sv= 1 J/kg.

would be needed to detect an elevated cancer risk in a population exposed to a dose of 10 mSv (the approximate dose of some medical radiodiagnostic procedures). As a general rule the population size needed to detect a risk with 95% confidence is inversely related to the square of the average population dose. If the average dose to the population is increased tenfold, the population size needed to detect a risk is reduced by a factor of 100.

Uncertainties in risk measurements at low dose can be reduced but not eliminated by using large study populations but this is impractical. Important additional information about risk might be obtained through study of patients receiving fractionated or chronic exposures, or studies of cohorts receiving chronic radiation exposures, either environmentally or occupationally (Puskin 2008).

Another source of uncertainty derives from the biological complexity of cancer. LNT and other dose-response options in radiation protection describe the relation between radiation dose and cancer incidence or mortality. The complex processes in cancer pathogenesis cannot be understood by analysis of dose-response curves. In view of the low-dose limitations of epidemiologic studies, biophysical studies at the cellular and sub-cellular levels have been used to better understand the shape of the dose-response curve at small doses (Brenner and Raabe 2001, Puskin 2009, Ulsh 2010). Cellular and sub-cellular studies have been important in understanding initiation and promotional events in carcinogenesis but reductionist approaches have serious limitations because they focus on the elements of the system rather than on the system as a whole. Cancer is more than a collection of abnormal cells. Tumor behavior and cancer risk cannot be predicted by studying individual cells.

Recently a system biology perspective has emerged as a way of looking at carcinogenesis. Through this lens tumors are viewed as complex selfassembled systems embedded in the larger complex system of the human body. The idea of a systems approach evolved from the growing understanding that cancer genes have important regulatory functions involving numerous gene regulatory networks. For example the *Myc* proto-oncogene subnetwork is a central regulatory system in the cell. The *Myc* proto-oncogene is a transcription factor that regulates expression of 15% of all genes. When it is mutated cancer results (Basso 2005). At the level of the cell, perturbations at one point in the gene regulatory network can have a rippling effect at other points in the network. Tumor cells have the capacity to communicate with each other and develop substances including angiogenesis factors for the benefit of the growing tumor (Kleinsmith 2006).

Reductionist approaches are not likely to be fruitful in clarifying the magnitude of risk at low doses because cancer is a complex disease and cellular changes do not necessarily translate into cancer mortality. Cellular and molecular events may be too far removed mechanistically to

have utility for predicting cancer risk (Ulsh 2010). The U.S. Courts recognize the difficulties linking cancer risk with cell injury. In *Dumontier et al. v. Schlumberger Tech* (2007) plaintiffs, claiming exposure to Cs-137 radiation exposure caused sub-cellular injury including DNA damage, sued even though there was no evidence of cancer. On appeal the Ninth Circuit Court of Appeals affirmed the Montana District Court decision in favor of Defendant arguing that cell damage does not necessarily lead to bodily injury. The U.S. Supreme Court declined to review.

The presence of small numbers of cancer cells does not necessarily mean a tumor will develop. Radiation carcinogenesis is a stochastic process. The dose of radiation determines the probability a radiogenic cancer will occur, not the severity of disease (National Research Council 2005; Mossman 2006). Tumors that begin to grow may stop growing for no apparent reason. Pseudo-disease is well documented in breast cancer and prostate cancer (Welch 2004). The detection of in situ lesions often lead to diagnosis of cancer, and the patient is treated even though these very small tumors were never destined to grow and require medical management. In cancer diagnosis it is often difficult to identify which cancers require medical attention and which ones are pseudo-disease and do not require medical intervention. This is a well known problem in breast and prostate cancer screening. Most ductal carcinoma in situ (DCIS) represents pseudo-disease of the breast and is not likely to progress to invasive disease. Approximately 50-70% of DCIS does not contribute to breast cancer risk (Welch and Black 1997, Welch 2004, Esserman et al. 2009).

Scientific efforts to resolve the shape of the dose-response curve at low doses have met with limited success in spite of significant advances in our understanding of the biology and clinical characteristics of cancer. Whether science will ever be able to resolve the LNT question is debatable. Without robust scientific and epidemiologic evidence at doses below 100 mSv a scientific confirmation of the LNT theory will remain out of reach.

# A POLICY (RISK MANAGEMENT) PERPECTIVE

Policy decision-making is complex when scientific evidence does not provide a clear decision path and stakeholders hold different values regarding alternatives. Economic, political and social factors can trump scientific considerations. The theory that best fits the scientific data may not be the theory of political choice. Science is an important component in decision-making, but it is not necessarily the key driver in the process (Pielke 2007).

The goal of risk management is to reduce risk. In practice it is the dose of the agent that is controlled, not the risk itself. The underlying assumption in risk management is that reduction of dose leads to a concomitant reduction in risk. Unfortunately there is little direct evidence to support this assumption from epidemiological studies in occupational

and environmental settings. In reality, the number of cancers averted for a given diminution in dose cannot be observed directly because risks are very small to begin with. Instead the number of cancer deaths averted is calculated based on a theoretically determined reduction in risk. Depending on the shape of the true dose-response curve, there may be little if any real change in risk when dose is reduced (Mossman 2006).

Several options are available to the decision-maker and risk manager to control risk. A strictly precautionary approach can be used to eliminate or avoid the risk entirely. This strategy puts heavy weight on risk reduction at high social costs. A goal to eliminate risks entirely may mean abandoning the technology altogether. More moderate approaches include avoiding unacceptable risks or costs and balancing risks and benefits. An unacceptable risk strategy gives weight to protecting the public health and environment at the expense of monetary and other costs of protection. In a management strategy to avoid unacceptable costs, limited resources are conserved at the expense of public health and environmental harms. A combination strategy seeks to balance costs and benefits (Coglianese and Marchant 2004).

Radiation protection has adopted universally a cost-benefit strategy in the form of an as low as reasonably achievable (ALARA) risk management philosophy. Under ALARA dose is reduced to levels as low as reasonably achievable below established dose limits given economic and social constraints (Mossman 2006). Under LNT theory and other monotonic dose-response functions reducing dose leads to a concomitant reduction in radiogenic risk. Reducing the dose to zero has the effect of eliminating the radiogenic risk. Implementation of ALARA is more complex however when considering non-monotonic functions such as the hormetic biphasic dose-response. A biphasic dose-response is characterized by a threshold dose below which the dose-response function is Ushaped. Reduction of dose below the threshold leads to beneficial effects (i.e., cancer incidence in the population is reduced). From a risk management perspective it is unclear how an ALARA program should be implemented when beneficial effects of radiation at sub-threshold doses are considered. The goal of any radiation risk management program including ALARA is to reduce radiogenic effects by managing radiation dose to the extent practicable given social and economic constraints.

Risk management is not a strictly scientific or engineering exercise. Social, political and economic considerations are keys to determining what is or should be achievable. Even though a dose is below the regulatory limit should it be reduced further? If so, what are the economic, political and social consequences of further risk reduction? Is there sufficient scientific evidence to suggest that reducing risk will result in a public health benefit? Should risks be reduced solely because we have the technical means to do so?

8

There is little argument that US radiation protection has been successful in protecting nuclear workers and the public from radiation exposure. But economic costs of risk management are considerable and raise serious questions about whether limited resources are being allocated optimally to address public health and environmental problems. One issue is LNT theory is used to justify dose reduction to levels at or close to zero above natural background based on the idea that no dose is acceptable. As doses approach natural background levels costs of further reductions become considerable. It is unclear these near-background dose diminutions provide concomitant public health or environmental benefits.

Cleanup of the Uravan Uranium site in Montrose County, Colorado illustrates how misinterpretation of the LNT theory can lead to excessive environmental cleanup costs. The 680-acre Uravan Uranium site began as a radium-recovery plant in 1912. From the 1940s to 1984, the plant operated as a uranium and vanadium processing facility. Operations left a large volume of waste, contaminating air, soil and groundwater near the plant. The EPA added the site to its National Priorities List in 1986, and the State of Colorado led the environmental cleanup effort. About \$127 million was spent from 1986 to 2008 to remove radioactive contamination from the site. At the close of the remediation project, residual radiation doses to hypothetical members of the public on the site approximated 0.02 mSv/y above natural background. Cleanup essentially returned the site to pristine conditions (Environmental Protection Agency 2008). But the public health benefits of the cleanup are unclear. An epidemiological study of the entire Uravan population from 1936-1984 showed no measurable public health effects of environmental radiation exposure. The overall Uravan mortality rate was 10% lower than the national average. Only an excess of lung cancer mortality in occupationally exposed uranium miners was observed and was attributable to high radon concentrations in the mines and cigarette smoking (Boice et al. 2007).

A 2000 study of US nuclear standards compared costs of soil cleanup at selected nuclear sites to achieve different soil cleanup levels (Table 2). Costs increased exponentially as cleanup levels become more restrictive. Cost differences among sites reflect site-specific differences including soil and building contamination and waste disposal options (General Accounting Office 2000).

**TABLE 2.** Estimated costs to achieve different soil cleanup levels at selected nuclear sites (General Accounting Office 2000)

Site	to 1 mSv	to 0.25 mSv	to 0.1 mSv
Nevada Test Site 1995	\$35 million	\$131 million	\$1 billion
Brookhaven National Laboratory Waste Facility 1998	\$16 million	\$24 million	\$64 million
Nuclear power plant 1997	\$0.17 million	\$0.3 million	\$1.4 million

Ratcheting doses downward eventually leads to a point of diminishing marginal returns in public health and environmental benefits (Breyer 1993). At what point does the cost of further dose reduction exceed derived benefits in terms of public health and environmental protection? LNT theory puts no lower bound on dose.

The idea that any dose is potentially harmful under LNT theory has also led to unwarranted fears about radiation. In one survey of primary care physicians in Pennsylvania, 59% of doctors identified fear of radiation as a major reason for their patients' refusal of mammography examinations. Fear of radiation-induced cancer or other health effects is one of several factors that might be considered by individuals who decline medical x-ray procedures. In the Pennsylvania study cost was also identified as a key factor why mammography was declined (Albanes *et al.* 1988). Women who refuse mammography may be denying themselves a key medical benefit by compromising early detection and the subsequent management of disease.

Following the Chernobyl accident in 1986, an estimated 100,000-200,000 Chernobyl-related induced abortions were performed in Western Europe. Radioactive fallout from the accident was widespread in Europe. Adults, pregnant women and children were exposed by ingesting contaminated foods. Fear of radiation injury was particularly acute among pregnant women. Perceptions of radiation risks affected personal choices about continuing pregnancies. In Greece, as in other parts of Europe, many obstetricians initially thought it prudent to interrupt otherwise wanted pregnancies or were unable to resist requests from worried pregnant women in spite of the fact that the abortions were unwarranted because radiation doses were much lower than necessary to produce *in utero* effects (Trichopoulos *et al.* 1987).

# THE POLICY-SCIENCE DYNAMIC

Science usually does not drive policy because scientific evidence is generally not convincing enough to support one policy option to the exclusion of alternatives. But science should provide policy makers with confident predictions of outcomes of distinct policy choices, which can then serve as the basis for informed decisions. Biological complexity however makes this difficult. Predicting health effects involves deep uncertainty because of the inherent complexity of cancer as a disease process and the difficulties in measuring very small risks.

It is unlikely LNT theory will be abandoned as the philosophical and practical foundation of radiation protection practice unless society decides that economic costs of current protection practices are unacceptably high and using a less conservative approach would not compromise the public health or environment. A philosophical shift to a less conservative policy would likely gain traction if clear evidence of a dose threshold

can be established. However, current epidemiological evidence can neither confirm nor eliminate the existence of a dose threshold (National Research Council 2005). There is scientific and epidemiological evidence in support of nonlinear theories but LNT theory remains the default option because countervailing evidence is not compelling (National Council on Radiation Protection and Measurements 2001). A practical threshold may exist if actual risks are substantially below those projected by LNT theory. Radiogenic risks at or close to zero may be considered negligible from a regulatory perspective. However adoption of a practical threshold for radiation protection purposes would almost certainly require epidemiological confirmation. A threshold level substantially above natural background levels might allow for relaxation of certain regulations like those associated with environmental cleanup. A threshold level below natural background would have no impact. Regulatory agencies like the EPA would be expected to move cautiously on the question of a policy change, and only on the basis of strong recommendations from internal and external advisory bodies. (Puskin 2009).

The existence of a threshold would likely impact radiation protection practice under the ALARA standard. Under LNT theory the ALARA dose floor is zero if LNT theory is interpreted to mean there is a non-zero risk at any dose. Radiation dose above natural background is reduced to the extent practicable given social and economic constraints under ALARA. In theory if resources are unlimited all dose above background should be eliminated. In practice resources are not unlimited and not all doses can be eliminated. An ALARA practice is considered satisfactory if the residual risk is deemed acceptable. If there is a dose threshold the dose floor is elevated to the threshold. In that case the balancing of costs against benefits to meet the ALARA standard terminates at the threshold dose floor. Expending resources to reduce dose further would be of no benefit and would be counter to the ALARA philosophy.

From a policy perspective LNT is on soft ground. The idea that any dose may be harmful and that no dose is considered safe has lead to a regulatory framework and philosophy characterized by public fear and increasing regulatory compliance costs. One concern is that valuable resources are allocated to progressively reduce doses to levels that provide no further public health or environmental protection. It seems prudent and reasonable to replace LNT theory with a less conservative, scientifically defensible dose-response policy if doing so reduces economic and social costs without compromising the protection of the public health and environment.

What would it take to demonstrate the cost-benefit advantage of a policy change? Assuming no change in worker or environmental dose limits, a scientifically defensible, nonlinear dose response would allow for less conservative ALARA practices as discussed above. Benefits in terms of

reduced compliance costs to realize higher residual risks can be quantified (Table 2), but measuring harms in terms of a reduction in public health and environmental protection would be very difficult. Radiogenic risks at doses near natural background levels cannot be measured reliably (National Research Council 2005). Because of the inherent difficulties and uncertainties in risk estimation small increases or decreases in dose are not likely to result in measurable changes in public health and environmental protection. That does not mean risks have not changed but if they have the change is too small to measure. Absence of evidence of benefit is not evidence of absence of benefit.

# **CONCLUSIONS**

There is considerable interest in revisiting LNT theory as a scientific basis for radiation protection practice. But, arguing the scientific merits of policy options is not likely to be fruitful because the science is not robust enough to support one theory to the exclusion of others. The nature of the scientific evidence is such that risk assessment at small effective doses (defined as <100 mSv) is highly uncertain, and several policy alternatives, including threshold and non-linear dose-response functions, are scientifically defensible. This paper argues for an alternative approach by looking at the LNT debate as a policy question and analyzes the problem from a social and economic perspective. It is unlikely LNT theory will be abandoned as the philosophical and practical foundation of radiation protection practice unless society decides that economic and social costs of current protection practices are unacceptable and using a less conservative approach would not compromise the public health or environment. A philosophical shift to a less conservative policy would likely gain traction if clear evidence of a dose threshold can be established. However, current epidemiological evidence can neither confirm nor eliminate the existence of a dose threshold.

#### REFERENCES

- Albanes D, Weinberg GB, Boss L and Taylor PR. 1988. A survey of physicians' breast cancer early detection practices. Preventive Medicine 17: 643-652
- Basso K, Margolin AA, Stolovitzky G, Klein U, Dalla-Favera R and Califano A. 2005. Reverse engineering of regulatory networks in human B cells. Nature Genetics 37: 382-390
- Boice JD, Cohen SS, Mumma MT, Chadda B and Blott WJ. 2007. Mortality among residents of Uravan, Colorado who lived near a uranium mill, 1936–84. J. Radiol. Prot. 27: 299–319
- Brenner DJ and Raabe OG. 2001. Is the linear-no-threshold hypothesis appropriate for use in radiation protection? Radiat Protection Dosimetry 97: 279-285
- Breyer S. 1993. Breaking the Vicious Circle: Toward Effective Risk Regulation. Harvard University Press, Cambridge, MA
- Coglianese C and Marchant GE. 2004. Shifting sands: the limits of science in setting risk standards. University of Pennsylvania Law Review 152: 1255-1360

Dumontier et al. v. Schlumberger Tech. Corp. 543 F.3d 567, 569 (9th Cir. 2007), cert. denied, 129 S. Ct. 1329 (2009).

- Environmental Protection Agency. 2008. Final Close Out Report: Uravan Mill and Adjacent Areas Montrose County, Colorado. Environmental Protection Agency, Denver, CO http://www.epa.gov/Region8/superfund/co/uravan/ (accessed September 2010)
- Esserman L, Shieh Y and Thompson I. 2009. Rethinking screening for breast cancer and prostate cancer. JAMA 302: 1685-1692
- General Accounting Office. 2000. Radiation Standards: Scientific Basis Inconclusive, and EPA and NRC Disagreement Continues. GAO/RCED-00-152. U.S. General Accounting Office, Washington, DC
- Hall EJ and Giaccia AJ. 2006. Radiobiology for the Radiologist Sixth Edition. Lippincott Williams & Wilkins, Philadelphia
- Kleinsmith LJ. 2006. Principles of Cancer Biology. Pearson Benjamin Cummings, San Francisco
- Mossman KL. 2006. Radiation Risks in Perspective. Taylor& Francis Publishing Group, Boca Raton FL
- Mossman KL. 2009. Policy decision-making under scientific uncertainty: Radiological risk assessment and the role of expert advisory groups. Health Physics 97: 101-106
- National Council on Radiation Protection and Measurements. 2001. Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation. NCRP Report No. 136, Bethesda, NCRP.
- National Research Council. 1983. Risk assessment in the federal government: Managing the process. National Academy Press, Washington DC
- National Research Council. 1994. Science and judgment in risk assessment. National Academy Press, Washington, DC
- National Research Council. 2005. Health risks from exposure to low levels of ionizing radiation: BEIR VII—Phase 2. National Academies Press, Washington, DC
- National Research Council. 2007. Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget. National Academies Press, Washington, DC
- Pielke Jr. RA. 2007. The Honest Broker: Making Sense of Science in Policy and Politics. Cambridge University Press, Cambridge UK
- Preston DL, Shimizu Y, Pierce DA, Suyama A and Mabuchi K. 2003. Studies of mortality of atomic bomb survivors. Report 13: Solid cancer and noncancer disease mortality: 1950-1997. Radiat Res 160: 381-407
- Puskin JS. 2008. What can epidemiology tell us about risks at low doses? Radiat Res 169:122-124
- Puskin JS. 2009. Perspective on the use of LNT for radiation protection and risk assessment by the U.S. Environmental Protection Agency. Dose-Response 7:284-291
- Sagan L. 1989. On radiation, paradigms, and hormesis. Science 245: 574, 621
- Trichopoulos D, Zavitsanos X, Koutis C, Drogari P, Proukakis C and Petridou E. 1987. The victims of Chernobyl in Greece: Induced abortions after the accident. British Medical Journal 295:1100
- Ulsh BA. 2010. Checking the foundation: Recent radiobiology and the linear no-threshold theory. Health Physics: 99: 747-758.
- Weinberg AM. 1972. Science and trans-science. Minerva 10: 209-222
- Welch HG. 2004. Should I be tested for cancer? University of California Press, Berkeley
- Welch HG and Black WC. 1997. Using autopsy series to estimate the disease "reservoir" for ductal carcinoma in situ of the breast: how much more breast cancer can we find? Ann Intern Med 127: 1023-1028