



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE AND MATERIALS
WASHINGTON, D.C. 20555-0001**

May 12, 2008

The Honorable Dale E. Klein
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: SUMMARY REPORT – 188th MEETING OF THE ADVISORY COMMITTEE ON NUCLEAR WASTE AND MATERIALS, APRIL 8 - 10, 2008, AND OTHER RELATED ACTIVITIES OF THE COMMITTEE

Dear Chairman Klein:

During its 188th meeting, April 8 - 10, 2008, the Advisory Committee on Nuclear Waste and Materials (ACNW&M) discussed several matters and completed the following letter to Dr. Dale E. Klein, NRC Chairman, from Dr. Michael T. Ryan, ACNW&M Chairman:

- “Advisory Committee on Nuclear Waste and Materials Low-Activity Radioactive Waste Working Group Meeting of February 13-14, 2008,” dated April 30, 2008.

HIGHLIGHTS OF KEY ISSUES

1. Working Group Meeting on the Effects of Low Radiation Doses – Science and Policy

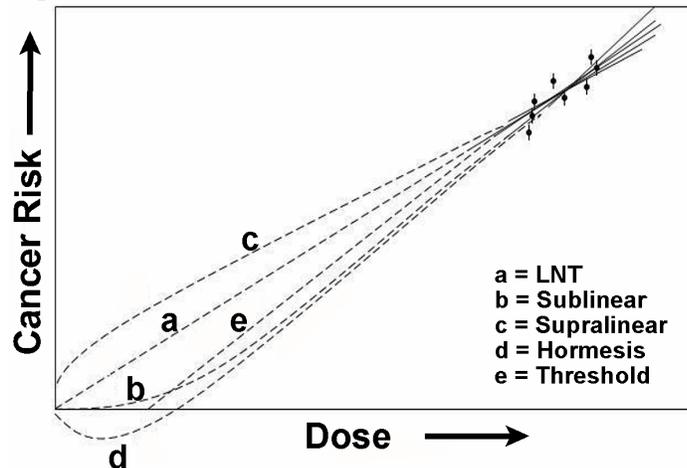
Representatives from academia, national laboratories, government and foreign agencies, and the NRC Office of Nuclear Regulatory Research were assembled by the Committee in order to discuss and share their current knowledge about the effects of low dose radiation and its ramification upon regulatory policy.

ACNW&M Chairman Dr. Michael Ryan gave an overview of the expected goals for the 2-day Working Group Meeting: (1) to discuss the Linear Non-Threshold (LNT) theory in light of current health physics, medical theory and cohort databases; (2) to review uncertainties about the presence or absence of health effects at low doses; (3) to examine the balance of science and policy in regulatory practice; and (4) to discuss possible alternative approaches to the LNT theory in regulatory practice.

NRC Commissioner Peter B. Lyons provided the opening remarks with a presentation titled “Communicating Risk at Low Doses.” Commissioner Lyons noted that LNT is treated as a fact, when in reality it may not be scientifically correct at very low doses. LNT is often seen as a conservative way to manage radiation risks, but it may not be conservative to use a model like LNT that has limited scientific basis and drives large expenditures of funds. LNT is also one of the main drivers of public fears about radiation. Everyone would be well served if we could move towards a stronger scientific basis for radiation effects at low doses.

Dr. Kenneth Mossman (Arizona State University) gave the keynote address, titled “The Linear Non-Threshold Theory (LNT) – Is It Time to Consider a Change in Regulatory Policy”? According to Dr. Mossman, the current state of the science is such that we do not yet have robust, statistically significant data to distinguish between candidate theories of biological response (see figure 1 below) at low doses (below 10 rem, or 100 mSv). The use of LNT to estimate cancer risks at very low doses leads the public to believe there is no safe dose; that any dose, no matter how small, carries risk. The translation from population risk to individual risk is the key question since we don't fully understand the nature of the risk factors. At very small doses, on the order of a few millisieverts per year, radiogenic risk is a very small contributor to the total cancer risk in any one individual. If the individual smokes or has a particular diet that would enhance risk, these factors tend to be far more important than any low dose radiogenic risk. With respect to the concept of collective dose, Dr. Mossman made a key observation that if the individual is not harmed, the population is not either. The way collective dose is used routinely is inappropriate, and the National Council on Radiation Protection and Measurements (NCRP), in its Report 121, and the International Commission on Radiological Protection (ICRP), in its Report 103, clearly discuss the limitations of collective dose. A key part of the collective dose constraint is that we should be cognizant of the fact that we are not dealing with infectious diseases where individuals can affect the health of other people. With respect to radiation dose we are all autonomous. In closing, Dr. Mossman offered several challenges to the workshop participants: Can low dose radiobiology answer the threshold question? What are the economic and societal costs of using an LNT-based system of protection? Is there a technical basis for abandoning a risk-based system of protection for a dose-based one?

Figure 1



Dr. Thomas S. Tenforde gave a talk titled “Perspectives of the NCRP on Important Issues in Understanding the Biological Effects of Low Radiation Doses.” Dr. Tenforde, the current President of the NCRP, noted that current knowledge is founded on relatively high-dose laboratory and human exposure data, and that regulations for public and occupational exposures are based on extrapolation of this high-dose information. With respect to public policy and regulatory implications, Dr. Tenforde noted the importance of resolving the question of whether conclusions can be drawn and predictive models developed for humans chronically exposed to low doses of radiation at or near background levels. Since 1990, NCRP has published numerous reports related to low dose effects. NCRP now proposes a definitive report on “Biological Effects of Low Radiation Doses and Implications for Human Health and Radiation Protection.” This four-year effort, if fully funded, would begin in 2010.

Dr. Mary H. Barcellos-Hoff (Lawrence Berkeley National Laboratory) gave a talk titled “U.S. Department of Energy (DOE) Low Dose Radiation Research Program – What Does it Tell Us About the LNT Hypothesis”? Dr. Barcellos-Hoff described how the DOE program evolved from an initial focus on single-cell systems to the study of multicellular (tissue) responses, with research on phenomena such as adaptive responses, bystander effects, and genomic instability. A key finding was that cellular gene expression profiles are significantly different in response to low versus high doses. Dr. Barcellos-Hoff noted that low doses elicit complex biology that may mediate carcinogenic risk. Radiation can cause abnormal cells and genomic instability, while at the same time radiation induces signals in tissues that counteract these adverse effects. One result is selective apoptosis (cell death), which kills aberrant cells before they can evolve to cancer. The tissue response can repress the cellular genome changes that promote cancer. Dr. Barcellos-Hoff concluded that predicting low dose effects requires study of biological responses at different levels of tissue organization.

Dr. Bernard Le Guen (Nuclear Plant Operations, Electricité de France; President, Health and Research Section, French Radiation Protection Society) gave a talk titled “Estimation of the Carcinogenic Effects of Low Doses of Ionizing Radiation – Insights about the LNT Hypothesis.” Dr. Le Guen presented a summary of key observations and results from the 2005 report by the French Academy of Sciences and National Academy of Medicine. While LNT may be useful for administrative radioprotection, its use for assessing low dose risks is not based on valid scientific data. All the data show the lower effectiveness of low doses and dose rates. The discrepancy between various experimental studies indicates there are several dose-effect relationships, not just one. As a summary of these studies, Dr. Le Guen showed a comparison of DNA damage caused by radiation (100 rad, or 1 Gy) versus damage that spontaneously arises in a cell (endogenous) without radiation. Radiation dose effects depend on the kind of cancer, the type of ionizing radiation, dose and dose rate, fractionation of irradiation, species affected, age, and individual sensitivity factors. Dr. Le Guen observed that epidemiological and biological data are compatible with the existence of a dose equivalent threshold, but cannot at this time demonstrate its existence or assess its value, which lies somewhere in the range from 1 to 6 rem (10 to 60 mSv). Dr. Le Guen concluded that collective dose cannot be used to evaluate cancer risk in a population.

Dr. Charles Land (National Cancer Institute) gave a presentation titled “Low Dose Extrapolation of Radiation Health Risks.” This talk examined some of the implications of uncertainty for radiation protection at low doses. He described what he called a “new paradigm” for the expression of radiation-related cancer risk, which was developed in NCRP Report 126, “Uncertainties in Fatal Cancer Risk Estimates used in Radiation Protection.” Under this new approach, statistical analyses are applied to the epidemiological data and later corrected for dosimetric uncertainty in the underlying data. This analysis yields estimated excess risk (EER) per 100 rad (1 Gy) (if linear) with confidence limits, resulting in a statistical uncertainty distribution. Dr. Land discussed the implications of applying the LNT theory to collective dose and risk. Given a low absorbed dose of 0.1 rad (1 mGy) to one million people, strict application of LNT would suggest 10 excess cancers would result. Dr. Land pointed out that we’d never be able to prove this by studying the million people, nor would it be possible to prove that the risk is much lower, if indeed it is. If we could agree there is no radiation-related cancer risk associated with doses below some specified threshold, then radiation protection might be easier and cheaper than it is today. A low-dose threshold would be difficult to prove for the same reasons that make it difficult to show the opposite. Experimental and epidemiological evidence does not preclude tissue-specific thresholds, but the evidence also does not support the existence of a universal threshold, operating in most tissues. Dr. Land presented the following conclusions:

(1) Most people would probably object to exposures [above background] unless the potential benefit clearly outweighs the potential risk, or they judge that the risk is truly “negligible;” (2) Information on risk and its upper probability limits are important to this process; and, (3) If the scientific consensus were that a threshold is very likely, that should be taken into account. Otherwise, the threshold possibility is mostly a distraction and can be largely ignored in radiation risk protection.

Dr. James Hammitt (Harvard School of Public Health) gave a talk titled “An Economic Perspective on Regulatory Decision-Making: Benefit-Cost Analysis Under Linear & Nonlinear Models.” This talk was a review of a basic economic perspective on decision making with regard to risks. The objective of economic decision making is to maximize well being, and individual well being depends on health, education, housing, food, entertainment, and other things. The economic objective in setting radiation exposure levels is to minimize the harm and maximize health benefit, and also to minimize control costs. This is accomplished by putting a monetary value on health improvement, and that monetary value is often described as a willingness to pay for the improvement. Dr. Hammitt noted that perceived harm is a central problem of health and environmental decision making under uncertainty. From the economic perspective, well being is defined and assessed by individuals. But there is extensive evidence that most people don’t understand probabilities very well, and make many inconsistent decisions in the face of probability and risk. People tend to like the idea that we could eliminate a risk, for example, the risk of lung cancer from radiation. Given that we face many other risks, why is it important to drive this one all the way to zero as opposed to reducing some others more? Dr. Hammitt concluded that economic evaluation can accommodate nonlinear exposure-response functions.

Dr. Jerome Puskin (U.S. Environmental Protection Agency (EPA)) presented an “EPA Perspective” on the meeting topic. He listed several reasons why LNT is used. Epidemiological studies have insufficient statistical power to test LNT at very low doses, and so far the biological research has not filled the gap left by epidemiology at low doses. Also, LNT is recommended by the ICRP, the NCRP, and the National Academy of Sciences (NAS). Dr. Puskin also noted there is evidence that a single mutation in a cell can increase the probability that the cell will become malignant. He discussed the concept of a threshold, which might be defined as a dose or dose rate below which no harm to any individual in a population would occur. A practical regulatory threshold might be considered if there were compelling evidence that, below this level, the risk is much lower than predicted by LNT, but not necessarily zero. Dr. Puskin reported that, contrary to some assertions, there is evidence for risks below 10 rem (100 mSv). For example, there is evidence of carcinogenic effects from prenatal x-rays 0.5-1 rad (5-10 mGy) and in scoliosis patients 0.4 rad (4 mGy). Dr. Puskin commented that ongoing epidemiological studies of chronically exposed cohorts (e.g., Chernobyl population, Techa River cohort, nuclear workers) may provide evidence of risk at 0.01-0.1 rad/day (0.1-1 mGy/day) or lower. One of the disadvantages of LNT is that perception of finite risk at low doses may cause the public to oppose beneficial nuclear technologies or to shun advisable procedures, but attempts to minimize risks in the absence of convincing evidence could damage the credibility of the radiation protection community. Before rejecting LNT, the EPA would want to see a scientific consensus from organizations such as the NAS, United Nations Scientific Committee on the Effects of Atomic Research (UNSCEAR), NCRP, and ICRP, along with acceptance among Federal agencies.

Dr. Vincent Holahan (NRC’s Office of Nuclear Regulatory Research) gave a talk titled “Effects of Low Radiation Doses – Science and Policy – NRC Staff Perspective.” Dr. Holahan initially described the NRC staff’s regulatory role and responsibilities with respect to low dose radiation effects and what might be needed to prompt changes in NRC’s regulations. An initial

consideration would be the backfit rule in 10 CFR Part 50, which states that a revision would have to prompt a substantial increase in the overall protection of public health and safety. Other things to consider include updated scientific information from basic research, such as the DOE Low Dose Radiation Research Program, research being done in Europe, and reviews of the extensive peer-reviewed literature. Regulatory changes might be prompted if a reduced threshold was found for eye lens opacification, or an increased incidence of non-cancer diseases, or if significant differences are found in gender and age sensitivity to radiation. At the end of 2008 a paper will be prepared for the Commission, laying out a series of options with resource requirements. Dr. Holahan concluded by saying that NRC's current regulations and standards adequately protect public health and safety. The adoption of new biokinetic models, risk coefficients, weighting factors, etc., will not significantly improve public health and safety.

Stakeholder Comments:

During this meeting several opportunities were given to other attendees to make comments or brief presentations consistent with the purpose and objectives of the working group session. A number of individuals presented oral comments for the record, and these included Mr. Lynn H. Ehrle (Senior Biomedical Policy Analyst for the Organic Consumers Association), Dr. Ted Rockwell (Radiation, Science, and Health), Dr. Dennis Wilson (SERV – Support and Education for Radiation Victims), Mr. Mike Boyd (EPA), and Dr. Noelle Metting (DOE). Mr. Ehrle and Dr. Rockwell also provided written materials that were made a part of the official record of the Working Group meeting.

Committee Action

The Committee plans to write a letter report summarizing the exchange of information during the Working Group Meeting on the Effects of Low Radiation Doses.

RECONCILIATION OF ACNW&M COMMENTS AND RECOMMENDATIONS WITH COMMITMENTS TO THE EXECUTIVE DIRECTOR FOR OPERATIONS, NRC

There were no recent responses from the Executive Director for Operations, NRC, to previous ACNW&M letter reports that required reconciliation by the ACNW&M.

PROPOSED SCHEDULE FOR THE 189th ACNW&M MEETING

No more topics will be heard by the Committee. The 189th ACNW&M meeting to be held on May 20 – 22, 2008, will be the Committee's last meeting and will be solely devoted to finalizing a letter report on Low Radiation Doses.

Sincerely,

/RA/

Michael T. Ryan
Chairman

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