UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE AND MATERIALS
WASHINGTON, DC 20555 – 0001

May 22, 2008

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

SUBJECT: WORKING GROUP MEETING ON THE EFFECTS OF LOW RADIATION DOSES

Dear Chairman Klein:

During its 188th meeting on April 8-9, 2008, the Advisory Committee on Nuclear Waste and Materials (ACNW&M, or the Committee) convened a Working Group Meeting (WGM) on the effects of low radiation doses. The objectives of this WGM were: (1) to discuss the Linear Non-Threshold (LNT) theory in light of current scientific information and data; (2) to review uncertainties about the presence or absence of health effects at low doses; (3) to gather information regarding the balance of science and policy in regulatory practice; and, (4) to discuss possible alternative approaches to the LNT theory in regulatory practice. Participants included NRC Commissioner Peter Lyons, professors from Arizona State University and the Harvard Center for Risk Analysis, representatives of the National Council on Radiation Protection and Measurements (NCRP), the National Cancer Institute, the U.S. Environmental Protection Agency, the French Radiation Protection Society, the Lawrence Berkeley National Laboratory, and the NRC staff.

In addition to the WGM, three Committee members also attended the annual meeting of the NCRP held April 14-15, 2008. This meeting was titled “Low Dose and Low-Dose Rate Radiation Effects and Models,” and included many presentations on topics related to effects of low doses of radiation.

Radiation dose to the average person in the U.S. from natural background is ~0.3 rem/yr (a large portion of this dose is from radon progeny in indoor air) [National Research Council, 2006, p. 4] leading to a 70-year “lifetime” dose of about 20 rem received at a steady rate of ~1 mrem/day. Recent information [ACNW&M, 2008, p. 133] indicates that the radiation dose from medical procedures to the average person in the U.S. is now about ~0.3 rem/yr leading to an additional average lifetime dose of ~21 rem. Most of the dose is received episodically at very high dose rates from medical procedures. Many medical procedures involving ionizing radiation use dose rates to portions of the body rather than the whole body that are orders of magnitude greater than the background dose rates.

Committee Observations

Terms such as “low dose” and “low dose rate” are not defined consistently. However, for the purposes of this letter these terms are defined to encompass the range of doses and dose rates

from situations typically regulated by the NRC, i.e., a lifetime dose less than 100 rem and a dose rate less than 10 mrem/day (including background).

Epidemiology Studies

- Epidemiologic data from multiple sources at doses ranging down to 10 rem (i.e., lower than the lifetime dose from background) indicate that the probability of stochastic effects such as cancer in a population is non-zero. However, these data are obtained from exposure primarily of Japanese A-bomb survivors, and some medical cohorts at dose rates many orders of magnitude greater than natural background [ACNW&M, 2008, pp. 56-58]. The probability of stochastic effects estimated from such data may not be valid at the dose rates relevant to radiation protection for workers and the public because cellular repair mechanisms may not have the same effectiveness at low dose rates.

- Ongoing epidemiological studies are being performed for cohort groups exposed at medium-to-low dose rates, including the Chernobyl population, Mayak workers, the Techa River cohort, the Semipalatinsk population, occupants in buildings in Taiwan that were constructed using steel contaminated with Co-60, and nuclear workers in several cohorts around the world. These studies have the potential to provide important information about long-term health effects of prompt and chronic exposures to radiation. However, there are uncertainties and confounding factors associated with these studies. The results may not have sufficient statistical power to elucidate the shape of the dose-response curve at the low dose rates.

DOE Low-Dose Radiation Research Program

- Interactions of ionizing radiation with biological material at the cellular level are complex. Effects on targeted cells, in which energy from ionizing radiation is deposited, are dose dependent, but non-targeted effects (i.e., effects in cells near the cells in which the energy from ionizing radiation is deposited) do not appear to be dose dependent. Previous biophysical models of radiation effects assumed independent action of ionization events in cells. Previous models also assumed each ionization event increases the probability of DNA damage. Most experiments related to non-targeted effects typically used doses greater than about 50 rad and dose rates much higher than the rate at which natural background radiation is received.

- The DOE Low Dose Radiation Research Program (http://www.lowdose.energy.gov/) has made a number of key findings that challenge previously held assumptions. There is strong evidence that ionization events in targeted and non-targeted cells are not completely independent. Non-targeted cells have surveillance mechanisms that dramatically affect the behavior of targeted cells and the development of cancer cells. The signaling from non-targeted cells appears to trigger responses to eliminate damaged cells. Recent research has shown the importance of studying in vivo biological response of tissue or an entire organism, rather than studying in vitro radiation effects in individual cells, to take such signaling into account. These results have been observed for high Linear Energy Transfer (LET) radiation such as alpha particles but not for low-LET radiation such as gamma rays.

- The DOE Low-Dose Radiation Research Program and similar programs elsewhere include radiation biology experiments at 1 to 2 rad, which is below the average lifetime

dose from natural background. As with the epidemiological studies discussed above, results from radiation biology experiments are typically obtained at dose rates several orders of magnitude above natural background. It is very difficult and costly to study radiation effects in ultra-low background environments (e.g., at levels below that typically received from the natural environment). As a consequence, it has not been possible to observe radiation-induced effects at dose rates at or close to background.

Shape of the Dose-Response Relationship

- Alternative dose-response theories converge in the range of about 50 to about 100 rem. Results from radiation epidemiological and biological research do not provide a basis for distinguishing among alternative dose-response theories at low doses and dose rates. At doses less than 10 rem, in addition to background, the difference in risk among the various dose response curves (i.e., sublinear, supralinear, threshold, hormetic, and linear) is not readily discernable.

- The Committee heard that a fractionated dose does not have the same effect as the same dose delivered all at once because repair mechanisms have time to work between the dose fractions. If there is a sufficiently long time interval between exposures the effects will not be additive.

- The existence of a dose threshold at doses and dose rates below the range where radiation epidemiology and biology provide useful risk information is uncertain. Questions remain about: (1) the magnitude of the dose (if any) at which the threshold occurs, (2) variation of thresholds in the population and thresholds in radiosensitive subpopulations, and (3) risk management from exposure to multiple sources if a threshold exists (i.e., doses from a single source may be below a threshold but the sum of doses from all sources may exceed a threshold).

Collective Dose and Health Effects

- The Committee reemphasizes its previous recommendations that collective dose is best used as a measure to compare alternatives in work practices or to compare alternatives impacting populations. However, collective dose is often used incorrectly when estimating radiological risk or when comparing alternatives impacting large populations. In particular, factors that can substantially influence the collective dose are usually inadequately represented. These factors include, for example, the age and gender of the exposed persons and the metabolic models for the radionuclides and the chemical species involved in exposures. Exposure scenarios often poorly represent variations in patterns, duration and extent of exposures to radiation and radioactive materials, and the factors that influence them such as lifestyle and sheltering.

- In its recent recommendations, the International Commission on Radiation Protection (ICRP) [ICRP, 2007, p. 51] stated, "…the Commission [ICRP] emphasizes that whilst the LNT model remains a scientifically plausible element in its practical system of radiological protection, biological/epidemiological information that would unambiguously verify the hypothesis that underpins the model is unlikely to be forthcoming…" Because of this uncertainty on health effects at low doses, the Commission [ICRP] judges that it is not appropriate, for the purposes of public health planning, to calculate the hypothetical number of cases of cancer or heritable disease that might be associated with very small

radiation doses received by large numbers of people over very long periods of time." Three ACNW&M Committee members believe that such calculations are not valid in any case.

The other ACNW&M Committee member believes that, given a policy decision to use one of the dose-response theories for radiation protection purposes, there is no technical basis for not using a collective dose estimate that includes the dose to all exposed individuals consistent with the selected dose-response theory to estimate health effects in a population as a measure of the potential impacts of radiation exposure. The NCRP has stated, "Since it is generally accepted that a dose of ionizing radiation, however small, has associated with it a risk of eliciting a deleterious biological response, there is no conceptual basis to exclude even the individual receiving the lowest dose from a calculation of collective dose" [NCRP, 1995, p., 47]. However, a number of requirements must be met for the collective dose underpinning the estimate of health effects to be valid and useful.

- Despite the differing views on the validity of using collective dose to calculate health effects in a population, the Committee unanimously believes there are technical reasons for not extending a collective dose estimate to calculate health effects. First, the extension involves additional computational complexities, especially if a non-linear dose-response relationship is used. Second, the extension to calculating health effects introduces substantial additional uncertainties because the correct dose-response relationship is not known at the dose and dose rates of interest. The Committee believes that calculation of collective dose meeting the requirements discussed above and the uncertainty in the collective dose, and comparison of these results to the range of collective doses from natural and man-made source, offers a simpler and more transparent alternative than calculating health effects.

Conclusions and Recommendations

1. The Committee concludes that the current state of scientific knowledge regarding low dose effects does not indicate the need for any changes to NRC's radiation protection standards or limits.

2. The Committee concludes that low dose radiation research programs should continue to fund studies on: (a) the effects of varying dose rates, (b) biological responses at dose rates less than 10 mrem/day and doses less than 100 rem, and (c) the biological response to micro-radiation environments (i.e., where background radiation is mostly eliminated). The results of such studies could lead to advances in the understanding of low dose effects and important implications to regulations concerning fractionated doses.

3. The Committee recommends that potential health impacts from routine and accidental releases of radioactive material, both real and projected, be measured by collective doses[1] to groups by location that meet the requirements of the ICRP and NCRP to the extent practical. These dose estimates should include uncertainty analyses. Such an approach should be used rather than absolute predictions of health effects. Collective

[1] The Committee does not intend to imply anything about the use of individual dose in this recommendation.

doses should not be used to calculate health effects but should be compared to collective doses from natural and appropriate man-made sources. Consideration should be given to developing additional guidance on approaches for valid calculation, comparison, and use of collective dose estimates.

4. The Committee recommends that the NRC staff keep informed about: (a) continuing developments in the epidemiological studies (cancer rates and life-span) of large cohorts of exposed populations, and (b) new findings in the area of low-dose and low dose-rate radiation effects. This should include work by the ICRP, NCRP, the United Nations Scientific Committee on the Effects of Atomic Radiation, and the DOE Low Dose Radiation Research Program and similar efforts elsewhere.

As a result of the approaching merger of the ACNW&M with the Advisory Committee on Reactor Safeguards (ACRS) on June 1, 2008, this is the final Committee letter to the Commission. On behalf of the entire Committee, I wish to thank the Commission for the opportunity for us and our 10 predecessors on the ACNW&M to be of service to the Commission since June 1988.

Sincerely,

/RA/

Michael T. Ryan
Chairman

References:

ACNW&M, 2005. Comments on ICRP Foundation Documents—A Followup to the ACNW&M November 3, 2004 Comments, Letter to N. Diaz from M. Ryan, July 1, 2005 [ML051820303].

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National Research Council, 2006. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII–Phase 2, Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation.

NCRP, 1995. Principles and Application of Collective Dose in Radiation Protection, NCRP Report No. 121 (November 30).

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NCRP, 1995. Principles and Application of Collective Dose in Radiation Protection, NCRP Report No. 121 (November 30)

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NAME	NColeman	NColeman	ADias	FGillespie	MRyan
DATE	5/22/2008	5/22/2008	5/22/2008	5/22/2008	5/22/2008

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Letter to the Honorable Dale E. Klein, Chairman, NRC, from Michael T. Ryan, Chairman, ACRS, dated May 22, 2008.

SUBJECT: Working Group Meeting on the Effects of Low Radiation Doses

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