



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, DC 20555 - 0001

ACNWR-0258

January 11, 2007

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

SUBJECT: REPORT OF THE FRENCH ACADEMY OF SCIENCES, "THE DOSE-EFFECT RELATIONSHIP AND ESTIMATING THE CARCINOGENIC EFFECTS OF LOW DOSES OF IONIZING RADIATION"

Dear Chairman Klein:

In response to an SRM dated February 9, 2006, during its 174th meeting on November 13-16, 2006, the Advisory Committee on Nuclear Waste (the Committee) heard a presentation from representatives of the French Academy of Sciences. The report was titled "The Dose-Effect Relationship and Estimating the Carcinogenic Effects of Low Doses of Ionizing Radiation." This report provided the Committee with excellent and detailed insights regarding the French Academy's study of the current state of radiation biology related to low dose exposures; their views regarding the linear no-threshold (LNT) theory of radiation injury; and the appropriate context for uses of the LNT.

Observations

The Committee offers the following observations from the presentation and discussion of the Academy's report:

1. The French Academy of Sciences report focuses on the radiobiological science and does not try to interpret these results in a policy context. In contrast, the BEIR VII report attempts to interpret the current state of knowledge into a policy context. The French Academy of Sciences presenters pointed out that the LNT theory of radiation damage can be appropriately used as a risk management tool but not as a risk assessment tool.
2. The presenters reported that collective dose is useful as a management tool for work planning and assessing worker exposure (ALARA), but should not be used as a risk assessment tool. Cancer risks for individuals or groups cannot be estimated using collective dose, nor can potential future cancer risk be projected from estimates of dose. The presenters stated that extrapolation of cancer risk using the LNT theory assumes that a very low dose administered to many people has the same carcinogenic effect as high doses administered to a small number of people. They further noted that this assumption does not have a scientific foundation, as UNSCEAR and ICRP have pointed out. The Committee has concurred with this view and reiterates it here.

3. The French Academy report, based on current data, raises doubts about the validity of using the LNT theory to estimate carcinogenic risks at doses less than 10 rem (< 100 mSv) and is even more skeptical of such estimates at doses less than 1 rem (< 10 mSv). However, an actual threshold in the probability of cancer as a function of dose cannot be demonstrated with data available today.

4. In contrast to the French Academy report, the BEIR VII report states:

“The [National Academy of Sciences] Committee concludes that the current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans.”

The BEIR VII report does not conclude that the LNT theory is correct but the data appear to be consistent with the LNT theory. The report does not rule out the possibility of a threshold.

5. A recent paper by several authors of the French Academy study compares their report with the BEIR VII report and the recent ICRP Report on cancer risk from low doses of radiation. One forward looking conclusion from this paper observes:

“The controversy related to the carcinogenic effect of low doses of genotoxic agents started over a decade ago (Abelson 1994, Ames and Gold 1997). However, the recent biological data have brought about new arguments which, when confirmed, would be convincing. The epidemiological studies have not yet been able to demonstrate a detrimental effect of low dose irradiation. They should be pursued and a meta-analysis of the available data should be carried out. The controversy between the reports should not be ignored. Discussion could clarify the problem and pave the way for new investigations and hopefully a consensus on many points. A few years ago the general impression was that it was important to obtain quantitative data regarding the effect of low doses but that it would always be impossible to reach a reliable conclusion. The perspectives have dramatically changed over the past few years. It clearly appears that in a decade or so we shall have conclusive data. In the meantime it would be proper to reconsider the ways the detrimental effects of low doses are assessed since an overestimation of the risks currently has a negative effect on the physical and mental health of the population.”

6. Radiobiology studies at the cellular, tissue, organ, and organism level are useful because, through these studies, understanding of the fundamental mechanisms of radiation injury and the response to such injury is being developed. Many factors influence biological responses to radiation at the cellular, tissue, organ

and organism levels. These include dose, dose rate, duration of exposure, and radiation quality. This information contributes to developing understanding of radiation carcinogenesis. As the Committee noted in its letter (dated November 8, 2006) to the Commission on the current efforts on low-dose research:

“This body of DOE research is unearthing interesting radiobiology on the mechanisms for radiation injury, repair, and responses to radiation mainly at the molecular and cellular level. However, much of the work is evaluating effects at doses several times to orders of magnitude above levels at which exposures to the public and to most workers are regulated. Extrapolation to lower doses and reconciliation with epidemiology studies have so far not been performed at a level of detail that would be directly useful in policy making or in revising current or developing new radiation protection standards at this time.”

7. The French Academy presenters stated that effects at low doses should not be extrapolated from effects at high doses because damage repair mechanisms at the cellular level can be quite different. Further, extrapolating observations at the cellular level to the tissue, organ, or organism level is also uncertain.
8. The French Academy report considered data from the Department of Energy (DOE) low-dose study, while in a letter dated July 15, 2005 from Raymond Orbach (Director, Office of Science, U.S. Department of Energy) to the National Academies it was pointed out that some epidemiological studies and new biological research were left out of the final deliberations of the BEIR VII Committee. It is not apparent to the ACNW that these differences in the data reviewed by either group would explicitly impact the ACNW's recommendations.
9. Exposure to a particular source cannot be evaluated in isolation. There are many sources of ionizing radiation (see public health statement for ionizing radiation at <http://www.atsdr.cdc.gov/toxprofiles/phs149.html>). Radiation exposure for any individual includes contributions from:
 - a. Terrestrial background
 - b. Cosmic radiation
 - c. Radon
 - d. Radioactive materials incorporated into the body
 - e. Medical exposures from diagnosis and therapy
 - f. Other man-made sources and human activities including air travel, consumer products, and nuclear power

The Committee has learned that the National Council on Radiation Protection and Measurements (NCRP) is undertaking a detailed study that will produce an update of NCRP Report No. 93, *Ionizing Radiation Exposure of the Population of the United States*, which was published in 1987. The scope of work includes all sources of radiation exposure: background radiation, industrial sources, medical patient, occupational, consumer products, and miscellaneous sources.

Conclusions and Recommendations:

1. Based on the Committee's review of the French Academy report and the BEIR VII report, the Committee finds the current state of knowledge does not warrant any change to current NRC radiation protection standards or limits.
2. The Committee affirms its earlier recommendations that the Committee and NRC staff should remain informed of continuing developments in this area. In support of this recommendation, the Committee plans a half-day Working Group session. The focus of the Working Group would be to give summaries of the state of knowledge of radiation biology with emphasis on implications for radiation risk models and radiation protection practice.
3. The Committee also reaffirms its previous recommendations that collective dose is only appropriate as a measure to be used in comparing alternatives and not as a method of estimating absolute cancer risk.

Sincerely,

/RA/

Michael T. Ryan
Chairman

References:

1. Dose-effect relationships and estimation of the carcinogenic effects of low doses of ionizing radiation, Académie des Sciences [Academy of Sciences] - Académie nationale de Médecine [National Academy of Medicine], André Aurengo¹ (Rapporteur), Dietrich Averbeck, André Bonnin¹ (†), Bernard Le Guen, Roland Masse², Roger Monier³, Maurice Tubiana^{1,3} (Chairman), Alain-Jacques Valleron³, Florent de Vathaire.¹ Member of the Académie nationale de Médecine. ² Correspondent Member of the Académie nationale de Médecine. ³ Member of the Académie des Sciences
2. 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 Board on Radiation Effects Research, Division on Earth and Life Studies, NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, THE NATIONAL ACADEMIES PRESS, Washington, D.C.
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3. September 30, 2005 Letter to The Honorable Nils J. Diaz Chairman U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001 "COMMENTS ON USNRC STAFF RECOMMENDATION OF THE USE OF COLLECTIVE DOSE"
4. OPINION The debate on the use of linear no threshold for assessing the effects of low doses M Tubiana, A Aurengo, D Averbeck and R Masse J. Radiol. Prot. 26 (2006) 317–324
5. ICRP 2004 ICRP Draft report of Committee I/Task Group. Low dose extrapolation of radiation related cancer risk
6. November 8, 2006 Letter to The Honorable Dale E. Klein, Chairman, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 titled "DOE LOW DOSE RADIATION RESEARCH WORKSHOP (VI)"
7. July 15, 2005 letter to Dr. Ralph Cicerone, President National Academy of Sciences, 500 Fifth Street, NW, Washington, DC 20001
8. National Council on Radiation Protection and Measurements, Program Area Committee on Radiation Measurements and Dosimetry PAC 6, Subcommittee on Radiation Expo-sure of the U.S. Population SC 6-2 (available at http://www.ncrponline.org/Current_Prog/SC_6-2.html)