

JOINT ACRS/ACNW SUBCOMMITTEE MEETING
HEALTH EFFECTS OF LOW-LEVEL RADIATION
MARCH 26, 1996
ROCKVILLE, MARYLAND

- TABLE OF CONTENTS -

	<u>Page</u>
1. Table of Contents	1
2. Agenda	5
3. Status Report	6

Cognizant ACNW Member: M. J. Steindler

Cognizant ACRS/ACNW Staff Member: R. Summers

Attachments:

1. Remarks by Gail de Planque, NRC Commissioner, November 29, 1994: "In Search of...Background." 1-19
2. BELLE Newsletter, Vol. 3, No. 1, July 1994: State of Research and Perspective on Radiation Hormesis in Japan. 20-30
3. Proposal by NCRP to NRC to produce an NCRP Report on the Critical Evaluation of the Linear, No-Threshold Assumption, funded by RES, no results as yet. 31-37
4. IAEA Letter of Invitation to "Discussion Group on Radiation, Science and Health," to be held April 22-23, 1996. 38-39
5. Article by James B. Muckerheide, Nuclear News, September 1995: The Health Effects of Low-Level Radiation: Science, Data, and Corrective Action. Transactions of the American Nuclear Society Session: Low-Level Radiation Health Effects, at the Meeting held October 29-November 2, 1996. 40-56
57-64
6. NCRP Report No. 121, Principles and Application of Collective Dose in Radiation Protection, November 30, 1995 (Preface and Conclusions only). 65-68
7. Article in European Journal of Nuclear Medicine, Volume 22, Number 5, May 1995, entitled: "The Issue of the Decade: Hormesis," by Dr. Myron Pollycove. 69-78
8. Biological Effects of Low-Level Exposures: Dose-Response Relationships; Chapter 11: Positive Health Effects of Low Level Radiation in Human Populations, by Dr. Myron Pollycove, published 1994. 79-98
9. Memorandum from Dr. Myron Pollycove, Visiting Medical Fellow to Donald A. Cool, NMSS, dated July 18, 1995: Recent Publication "Confirming" Linear, No-Threshold Theory. 99-115
10. LLW Forum News Flash, dated March 6, 116-118

1996: Health Physics Society Adopts
Position re Low Doses of Radiation.

11. The Health Physics Society's Newsletter, June 1995, devoted to short essays on the linear, no-threshold hypothesis by a number of contributors, including Ronald L. Kathren. 119-134
12. Viewgraphs from presentation to NRC staff by Charlie Willis, NRR on March 12, 1996: Health Physics Society: Don't Quantify Risk Below 5 rem/year or 10 rem Lifetime. 135-155
13. Nucleonics Week, January 25, 1996: "European Union to Adopt New Radiation Protection Norms." 156-157
14. Nucleonics Week, November 23, 1995: "French Academy Rejects 1990 ICRP Norms as Not Based in Science." 158-160
15. Memorandum from Bill M. Morris, RES, to David L. Morrison, RES, dated October 31, 1995: Effects of Low-Level Radiation. 161-169
16. Article by R. Piispanen, Environmental Geochemistry and Health (1995): "Radiation Hormesis: Fact or Fiction?" 170-177
17. Article by Zbigniew Jaworowski, in Regulatory Toxicology and Pharmacology, October 1995: "Stimulating Effects of Ionizing Radiation: New Issue for Regulatory Policy." 178-187
18. Article by Zbigniew Jaworowski, in Nukleonika, August 1995: "Beneficial Radiation." 188-198
19. Excerpts from Report of the United Nations Committee on the Effects of Atomic Radiation to the General Assembly, 1994 (Conclusions), and Annex B: "Adaptive Responses to Radiation in Cells and Organisms." 199-243
20. "Setting Standards for Radiation Protection: A Time for Change," by H. Wade Patterson and David P. Hickman, under the auspices of LLNL. 244-251

20. Article by Dr. Kenneth T. Bogen, LLNL, February 1996: "A Cyclodynamic Two-Stage Model That Predicts Radon Hormesis (Decreased, then Increased Lung-Cancer Risk vs. Exposure)." 252-297
21. Article by Leonard Sagan, EPRI, in Radiation Physical Chemistry, Issue 37, 1991: "Radiation Hormesis: Evidence for Radiation Stimulation." 298-302

JOINT ACRS/ACNW SUBCOMMITTEE MEETING
HEALTH EFFECTS OF LOW-LEVEL RADIATION
MARCH 26, 1996
ROCKVILLE, MARYLAND

- AGENDA -

	<u>Presentation</u> <u>Length</u>	<u>Time</u>
I. Introduction - Dr. Steindler	5 min	1:30-1:40 p.m.
II. Office of Nuclear Materials Safety and Safeguards C. Paperiello, Director, NMSS	15 min	1:40-1:55 p.m.
III. Implications of new data for linear, no-threshold theory J. Muckerheide, Massachusetts Emergency Management Agency	15 min	1:55-2:10 p.m.
IV. NCRP Views and Collective Dose Report (NCRP 121) R. Kathren, Washington State University	15 min	2:10-2:25 p.m.
V. Recent medical studies showing effects of low-level radiation M. Pollycove, NRC Visiting Medical Fellow	15 min	2:25-2:40 p.m.
VI. Round-table Discussion	50 min	2:40-3:30 p.m.

JOINT ACRS/ACNW SUBCOMMITTEE MEETING
HEALTH EFFECTS OF LOW-LEVEL RADIATION
MARCH 26, 1996
ROCKVILLE, MARYLAND

- STATUS REPORT -

PURPOSE

The Subcommittee will hear presentations on the health effects of low-level radiation and on the regulatory implications of potential changes to the linear, no-threshold theory. Speakers will be Carl Paperiello, Director, Office of Nuclear Material Safety and Safeguards; Dr. Myron Pollycove, NRC Visiting Medical Fellow; and two invited speakers: James Muckerheide and Ronald Kathren (see below).

The relative risk of exposures to radiation is at the heart of NRC regulation, and the linear, no-threshold hypothesis has been the basis for setting exposure limits. For many years, this hypothesis was accepted without major objections, partly because determining the effect of low doses is so difficult, partly because it takes a long time for health effects from doses to appear, and partly because it is in line with the conservative path generally taken by this industry and its regulators. However, in the past few years, requests for reconsideration of this hypothesis have increased, based on new epidemiological and medical studies.

As this is an issue that, with some exceptions, is not being actively addressed by the staff, the Subcommittee will want to determine if there is a need to pursue the subject independently, perhaps as part of a larger initiative on risk-informed regulation, and/or to recommend that the staff do so.

NRC ACTIVITIES

Dr. Gail de Planque, former NRC Commissioner, had a strong interest in this subject and, at the NRC Workshop on Site Characterization for Decommissioning on November 29, 1994, presented a paper entitled: "In Search of...Background". [pp. 1-19]. Her paper asked how both background and residual radioactivity should be defined or measured, and "given that the risk associated with a 15 mrem residual dose adds very little to the risk...how much money and effort should be spent not only to clean up to this level, but to assure compliance?"

The NRC has the following activities:

- participates in the ISCORS (Subcommittee of the Interagency

Scientific Committee on Radiation Standards), which is debating whether to begin BEIR VII on the linear, no-threshold theory now or delay it until more studies are completed. The most recent meeting was March 20, 1996.

- has supported the BELLE (Biological Effects of Low-Level Exposures) Newsletter, published by the Massachusetts School of Public Health, [pp. 20-30].
- has funded a proposal from the National Council on Radiation Protection and Measurements (NCRP) to make a Critical Evaluation of the Linear-No Threshold Assumption [pp. 31-37], but has not yet received results from it.
- will attend an Informal Discussion Group on Radiation, Science and Health that will meet at the IAEA in Vienna, Austria, on April 22-23, 1996 [pp. 38-39]. The intention of this discussion is to explore the current policies of dealing with small radiation exposures above the unavoidable background exposure, as requested by experts from the various involved disciplines, and the discussion will include the need for an overall strategy and specific activities for further action.

NRC is considering sponsoring some joint research with other government agencies but has not made definite commitments.

AMERICAN NUCLEAR SOCIETY ACTIVITIES

The ANS has devoted several sessions at recent meetings to low-level radiation health effects. At the November 1995 meeting, there were four sessions on this topic, plus "Biology Research and Beneficial Effects," and a panel on "Needs for Research, Organization and Corrective Actions." James Muckerheide, State Nuclear Engineer, Massachusetts Emergency Management Agency, chaired the sessions [pp. 40-56] and is the author of an article in the ANS publication Nuclear News on this subject. His article states that "Statistically significant data show below-normal adverse health effects (i.e., health benefits) at low-to-moderate doses compared with unexposed populations. These data, however, are effectively obscured when linear relationships are arbitrarily imposed on these non-linear data..." [pp. 57-64]. Mr. Muckerheide is an invited speaker to the Subcommittee meeting.

NCRP ACTIVITIES

The NCRP issued Report No. 121: "Principles and Application of Collective Dose in Radiation Protection" on November 30, 1995. The report states that the application of collective dose

"assumes linearity of dose response." [pp. 65-68] Ronald Kathren, Chairman of NCRP Scientific Committee 1-3, Collective Dose, who published the report, is an invited speaker. He also contributed to the Health Physics Society Newsletter devoted to the linear, no-threshold theory (see below).

The President of NCRP, Mr. Charles B. Meinhold addressed the local (Washington) Chapter of the Health Physics Society on March 12, 1996, on the topic: "Uncertainty and Risk Estimates." His position (obtained second-hand) was that, although there may be evidence in the future that not all low doses are harmful, the prudent position for NCRP is to assume they are harmful until substantial scientific proof is in hand to show otherwise. Mr. Meinhold has been invited to the Joint Subcommittee meeting but has not indicated whether he will attend.

The topic for the 32nd Annual NCRP meeting on April 3-4, 1996 is: "Implications of New Data on Radiation Cancer Risk."

MEDICAL RESEARCH

Dr. Myron Pollycove, NRC Visiting Medical Fellow, is an invited speaker to the Subcommittee meeting. He has published several papers on the subject of radiation-induced hormesis [pp. 69-98] and will represent the NRC at the IAEA meeting (see above). He reviewed a paper considered by some to confirm the linear theory and concluded that "the data demonstrate no evidence of association between radiation dose and mortality from all causes or from all cancers including mortality from leukemia other than chronic lymphatic leukemia (CLL)." His analysis cites the U.S. Nuclear Shipyard Worker study reported in 1991 of 700,000 workers, including 106,851 monitored nuclear workers, that "demonstrated a highly significant -0.24 risk decrement (-16 SD) of standardized mortality from all causes, no increase of leukemia or lymphatic and hematopoietic cancers, and the absence of any healthy worker effect." [pp. 99-115]

HEALTH PHYSICS SOCIETY ACTIVITIES

In the March 1996 issue of the HPS Newsletter, the HPS published its position that health risks should not be quantified for radiation doses exceeding background doses by less than 5 rem per year or 10 rem during a lifetime [pp. 116-118].

The HPS Newsletter for June 1995 was devoted to the linear, no-threshold paradigm. Although responses were invited from both sides of the issue, almost all the responses received refuted the theory. Ronald Kathren's contribution concludes that: "What we know (or should know) and bear in mind in our standards-setting process is that the linear, no-threshold hypothesis does not

apply to all radiation dose responses, and that for some effects there may in fact be a threshold, or a nonlinear response." [pp. 119-134]

Charles Willis (NRR) gave a brown bag seminar at NRC at which he discussed the recent HPS position [pp. 135-155]. He covered many of the scientific studies showing no evidence of detriment at low doses, as well as the evidence for hormesis and the handling of studies showing this effect. He will attend the Subcommittee meeting and answer any questions concerning the HPS position.

INTERNATIONAL RESEARCH

The European Union recently adopted new basic safety standards for radiation protection that incorporate the 1990 recommendations of the International Commission on Radiation Protection (ICRP) to lower the limit of exposure to workers from 50 Msv/year to 20 Msv/year [pp. 156-157]. France's Academy of Sciences strongly opposed the adoption of these standards, saying there was "no scientific justification." However, the report conceded that the decision might have to be judged on other criteria besides strict scientific justification [pp. 158-160].

The French Institut de Protection et de Sûreté Nucléaire (IPSN) commissioned a study by the National Radiological Protection Board (NRPB) of Great Britain to present an updated review of the current state of knowledge relevant to the assessment of the risk of radiation-induced cancer at low dose rates. The main source of data for the study, published in July 1995, was the Life Span Study of the Hiroshima and Nagasaki survivors, as well as patients irradiated for medical purposes, including exposure of pregnant mothers. The study concluded that "there is little basis for arguing that low radiation doses (about 10mGy) would have no associated cancer risk and that, in the present state of knowledge, it is appropriate to assume an increasing risk with increasing dose."

This study was reviewed by Dr. Shlomo Yaniv, Senior Technical Advisor, NRC Office of Nuclear Regulatory Research, who agreed with its conclusions. His paper [pp. 161-169] states: "There is some evidence that low dose and low dose rate radiation may produce beneficial effects...[However] The existence of adaptive response does not contradict the no-threshold conclusion, since in a complex organism both deleterious and beneficial effects can be induced by the same agent." Dr. Yaniv is expected to attend the Subcommittee meeting.

Studies of radiation hormesis have appeared in other international publications. A paper in Environmental Geochemistry and Health (1995) by R. Piispanen of the Institute of geosciences and Astronomy, University of Oslo, entitled:

"Radiation hormesis: fact or fiction?" concludes that more work is required, particularly in the area of "the separate effects of various forms of ionizing radiation and radioactivity...since cancerous diseases can simultaneously show a positive correlation with radon but a negative one with background gamma radiation." [pp. 170-177]

Two papers have been written by Zbigniew Jaworowski, Central Laboratory for Radiological Protection in Poland, one entitled: "Beneficial Radiation," [pp. 178-187] and the other: "Stimulating Effects of Ionizing Radiation: New Issue for Regulatory Policy." [pp. 188-198] Both papers discuss the March 1994 UNSCEAR Report [pp. 199-243] that, "after 12 years of deliberation, dispels the common notion that even the smallest dose of radiation is harmful." Jaworowski also discusses the Chernobyl accident and a number of studies that refute the linear hypothesis.

OTHER RESEARCH

A paper by H. Wade Patterson and David P. Hickman, in a study sponsored by Department of Energy through Lawrence Livermore National Laboratory (LLNL), entitled: "Setting Standards for Radiation Protection: A Time for Change," concludes that "in the spirit of true science it is obligatory to reject this [linear hypothesis] policy. The promulgation of standards for radiation protection must be based on scientific observation rather than on unsupported assumptions and subsequently begged assertions." Patterson recommends a re-examination "under the auspices of some entity other than those groups responsible for the present standards," due to conflict-of-interest considerations, and that "good scientific principles should be employed in arriving at logically and unequivocally stated concepts." [pp. 244-251]

Another study done by Dr. Kenneth T. Bogen, also at LLNL, has produced a mechanistic 2-stage model that "realistically accounts for radon-induced...DNA damage" and concludes that "current estimates of cancer risk posed by household radon exposures appear to be more uncertain than previous calculations indicate". [pp. 252-297]

And finally, a paper, written by Leonard Sagan, Electrical Power Research Institute, April 1990, presents an excellent basic description of hormesis, entitled "Radiation Hormesis: Evidence for Radiation Stimulation and Speculation Regarding Mechanisms." It agreed on the possible existence of an agent that simultaneously creates a hazard and a benefit and quoted Professor Thomas Kuhn in concluding that "Normal science often suppresses fundamental novelties because they are necessarily subversive of its basic commitments...Nevertheless, so long as those commitments retain an element of the arbitrary, the very

nature of normal research ensures that novelty shall not be suppressed for very long." [page 298-302]

ACTION

At a minimum, the Subcommittee will want to inform the Full Committees of their meeting on this subject and their recommendations for further action. These could include:

1. That no further action be taken at this time but that the Subcommittee staff continue to stay abreast of developments and schedule additional meetings when necessary.
2. That the Subcommittee schedule a second meeting to look at interagency harmonization, certain to be a major problem if the NRC decides to take some initiative in this area.
3. That the Subcommittee undertake a broader review of risk-informed regulation, and include this as a subpart of that discussion.
4. That one or both Full Committees take the subject up for review now, with the goal of making recommendations for action by the Commission and/or the staff.