ACNW-0129

MINUTES OF THE 108TH ACNW MEETING MARCH 23–25, 1999

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CERTIFIED

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6/15/99 BY B. JOHN GARRICK

CERTIFIED MINUTES OF THE 108TH MEETING OF THE ADVISORY COMMITTEE ON NUCLEAR WASTE MARCH 23–25, 1999 ROCKVILLE. MARYLAND

The U.S. Nuclear Regulatory Commission's (NRC's) Advisory Committee on Nuclear Waste (ACNW) held its 108th meeting on March 23–25, 1999, at Two White Flint North, Room T-2 B 3, 11545 Rockville Pike, Rockville, Maryland. Notice of this meeting was published in the *Federal Register* on March, 8, 1999, Volume 64, No. 44, pages 11071-11072 (Appendix I). The purpose of this meeting was to provide a forum for attendees to discuss and take appropriate action on the items listed in the agenda (Appendix II). The entire meeting was open to the public.

A transcript of selected portions of the meeting is available in the NRC's Public Document Room at the Gelman Building, 2120 L Street, NW, Washington, DC 20003-1527. Copies of the transcript are available for purchase from Ann Riley & Associates, Ltd., 1250 I Street, NW, Suite 300, Washington, DC 20005. Transcripts are also available for downloading from, or reviewing on, the Internet (http://www.nrc.gov/ACRSACNW).

ATTENDEES

ACNW members who attended this meeting include Dr. B. John Garrick, ACNW Chairman, Dr. Charles Fairhurst, Dr. Raymond G. Wymer, and Dr. George M. Hornberger. For a list of other attendees, see Appendix III.

I. CHAIRMAN'S REPORT (Open)

[Richard Major was the Designated Federal Official for this portion of the meeting.] Dr. B. John Garrick, Committee Chairman, convened the meeting at 8:35 a.m. and briefly reviewed the schedule for the meeting. He stated that the meeting was being conducted in conformance with the Federal Advisory Committee Act. He also stated that the Committee had received requests from James Muckerheide, Myron Pollycove, and Theodore Rockwell of Radiation, Science, and Health, Inc., to make oral statements during the meeting. He asked that members of the public who were present and had something to contribute to the meeting to inform the ACNW staff so that time could be allocated for them to make oral statements. He noted the following items he believed were of interest:

- The Department of Energy (DOE) plans to spend \$64.6 million on low-dose radiation research over the next 10 years, according to a Research Program Plan prepared by the office of Biological & Environmental Research. The program aims to answer fundamental questions about how cells react to low radiation doses and whether there is a threshold below which the radiation has no damaging effect. Funding for the program's first year is \$12 million, and the department has received about 160 "pre-applications" requesting first-year funds. According to DOE officials, about half of those who submitted the one-page pre-applications outlining their proposed research will be encouraged to submit full-fledged applications, due in mid-April 1999.
- Texas is at a crossroads with its low-level waste (LLW) management policy and could make major changes with bills introduced in the legislature this year. The State's project to site a disposal facility in Hudspeth County fell apart last year when regulators denied a license application prompting advocates to seek alternatives. Since then, Texas has been looking at a concept called assured isolation (AI) to deal with LLW. AI is similar to decay in storage. In both cases, radwaste would be stored in an above-ground structure for perhaps hundreds of years until at least some of it decayed to very low levels and could be disposed of at a regular sanitary landfill.
- The NRC is considering a request from Ohio to become an Agreement State and take over regulatory responsibility for some nuclear materials. The agreement could become effective in July 1999, thus making Ohio the 31st Agreement State.
- DOE must pump out 98 percent of the 6 million gallons of liquid waste remaining in 29 single-shell tanks at the Hanford site by September 30, 2003, under a draft consent decree signed last week by DOE and Washington State. The consent decree establishes a "court-enforceable" schedule for pumping liquid nuclear waste out of the underground tanks. To date, liquid waste has been removed from 119 of the 149 single-shell tanks at Hanford.
- The Environmental Protection Agency (EPA), responding to longstanding complaints by the nuclear industry, says it plans to roll back its regulation of commercial mixed low-level radioactive wastes and rely on the NRC to ensure safe storage and disposal. The EPA announcement, detailed in an advance notice of proposed rulemaking dated March 1, 1999, is aimed at addressing industry concern about dual regulation of mixed toxic and low-level radioactive waste—as hazardous waste by EPA and as nuclear waste by NRC.

II. LOW LEVELS OF IONIZING RADIATION (OPEN)

[Howard J. Larson was the Designated Federal Official for this portion of the meeting.]

After brief introductory comments by Dr. Garrick, Commissioner Dicus, in her keynote address, presented comments relating to the importance of the linear, non-threshold (LNT) hypothesis to the NRC's objective of developing a risk-informed, performance-based approach to regulations.

She stated that the radiation protection standards must be both protective of public health and safety and the compliance costs justified by the risk, should the standards not be met.

She pointed out that there is a whole spectrum of views, from those observing that the standards are not strict enough, to those that believe the standards are too strict, resulting in rising compliance costs as the acceptance levels go down. As an example, she cited costs that could be associated with the demonstration of compliance of a decontaminated site with unnecessarily restrictive license termination standards. She noted that the costs to demonstrate compliance are not borne by the regulatory agencies but are imposed upon the rate payers and tax payers.

Regarding the risk of health effects from low-level ionizing radiation, Commissioner Dicus posed the question as to how the Commission should factor this risk into radiation protection standards as it moves toward a risk-informed, performance-based regulatory approach, particularly in light of the uncertainty associated with these health effects.

Dr. Arthur C. Upton, Chairman of the National Council on Radiation Protection and Measurements (NCRP) Scientific Committee (SC) 1-6, made a presentation on the draft NCRP SC 1-6 report, "Evaluation of the Linear Non-threshold Dose-Response Model." This report was funded by the NRC. The studies reviewed in this report encompassed the fields of epidemiology, cellular and molecular biology, and genetics. He mentioned a number of sets of data that supported the LNT hypothesis and others that cast doubt on its validity. However, the draft NCRP SC 1-6 report appeared to many as representing a defense of the LNT model of radiation carcinogenesis at low doses.

Dr. Upton discussed several types of cancers and the attempt to develop meaningful, related models for the determination of low-dose effects. After pointing out their vagaries, he stated that no one model is overwhelmingly consistent with all of the data that SC 1-6 had examined, and that for some types of cancers and mutations, the LNT model appears to be plausible. The determination of what constitutes the appropriate model is the issue. Upon completion of his presentation, Dr. Upton responded to several questions and comments concerning the use of epidemiological and animal data to prove the LNT hypothesis; the amount of data that is available for analysis; the lack of correlation between cancer rates and natural background levels; the lack of data in the centigray range and the population size

necessary to demonstrate risk in that range; the fact that the works of Messrs. Luckey and Cohen were not included in the SC 1-6 draft; and the application of results of scientific research to the NRC's risk-informed, performance-based regulatory approach. A comment was made from the floor that not all of the available data was analyzed for the SC 1-6 draft report.

Indicative of the polemic since there is no complete understanding of the processes by which radiation exposure may lead to cancer were the comments from the floor of Dr. Myron Pollycove, who found the SC 1-6 draft report to be seriously flawed and Dr. Shlomo Yaniv, who stated that the SC 1-6 conclusions are valid.

Dr. Upton agreed to review the SC 1-6 draft report to make certain that it was balanced insofar as it included references by those who scientifically disagree with the validity of the current LNT hypothesis.

Dr. Marvin Frazier, Director of the Health Effects & Life Sciences Research Division, Office of Biological and Environmental Research, DOE, presented the new DOE low-dose research program.

He pointed out that this is a joint program between the Office of Science (OS) and the Office of Environmental Management (OEM), with OS providing the basic research effort and OEM providing the applied research effort. Dr. Frazier stated that the fundamental question the program is intended to address is whether there are safe levels of exposure to radiation, that is, levels at which individuals need not be concerned.

To determine these levels, Dr. Frazier stated that DOE would need to look at endogenous processes—the processes used to repair radiation damage in the cell. One of the issues that will be addressed in this program is the qualitative and quantitative differences between oxidative damage and low-level radiation damage. In addition, the program will also address the question of a threshold for low-dose radiation, issues of genetic factors, susceptibility, as well as how to better communicate their associated risks. Regarding communication of risks, Dr. Frazier stated that the program will communicate results much more readily than in the past in order to engage people and obtain feedback as the research is performed.

Dr. Frazier then discussed the research program and the advisory board, the Biological and Environmental Research Advisory Council. This is a 10-year program and will be accessible to policy makers, scientists, and legislators. He stated that the plan is a living plan that will be modified as the program progresses. Dr. Frazier stated that the researchers would be studying the effects at many levels, from DNA to whole organisms, and will look at the mechanistic aspects to try to quantify them. Insofar as epidemiology is concerned, Dr. Frazier stated that the DOE program was depending on other studies to provide that information.

He stated that one reason the program would be addressing susceptibility to radiation is that there might be highly susceptible groups driving the low-dose responses. He added that

although we currently have the tools to address this issue, what to do with the answer was a question for the policy makers to decide because of the ethical considerations involved.

Dr. Frazer addressed communication of research results. He stated that DOE was considering education modules for schools as well as interactions with the scientists to make sure that they are providing the right information. DOE intends to also work with regulators and legislators to try to further develop this process over the course of the next 10 years so that it really does make a step change in risk estimation processes.

After addressing the development of the human genome project and the status of chip technology and advances in related instrumentation, Dr. Frazier restated DOE's commitment to interact with interested Government agencies and advisory and scientific groups to gain input for his program.

Dr. Frazier responded to several questions and comments concerning low-dose radiation research and the uncertainty associated with being able to measure health effects at low doses. He also responded to questions regarding gaps in the research and how to integrate the various research efforts.

Dr. Charles Land, Health Statistician, Radiation Epidemiology Branch, National Cancer Institute, gave a presentation on radiation epidemiology studies. His conclusion was that it is virtually impossible to demonstrate the existence of a low-dose threshold for radiation carcinogenesis by epidemiological means because of the biostatistical uncertainties associated with background levels of cancer.

He did show data that suggested that breast cancer risk from ionizing radiation is not reduced by protraction of the exposure. Dr. Land stated that if we only had the data below a tenth of a Sievert (10 rem), we would have no reason to believe that there is an excess risk associated with radiation. He also discussed how to calculate excess relative risk, classical distributions, and regression analysis.

Upon completion of his presentation, Dr. Land responded to several questions and comments concerning other methods of statistical analysis, such as Bayesian analysis, discrete histograms, and Poisson distributions. He also responded to questions about the life span incidences of Japanese people who were not in Hiroshima and Nagasaki, noting specifically that the A-bomb survivors have a lower cancer incidence rate and a longer life span than those Japanese who were not in Hiroshima and Nagasaki at the time of the bombing—a healthy survivor effect. In addition, he addressed questions relating to the shipyard worker study (which had been presented to the Committee at an earlier LNT working group meeting).

Dr. Evan Douple, Director of the National Academy of Sciences (NAS) Board on Radiation Effects Research, BEIR VII, discussed the two phases of the NAS BEIR VII study: (1) the scoping study, requested and sponsored by the EPA, and (2) the reassessment of all data and

information since the 1990 BEIR V report, sponsored by the Environmental Protection Agency (EPA) and the NRC in cooperation with other agencies.

Dr. Douple stated that the Phase I Scoping Committee produced a report titled "Health Effects of Exposure to Low Levels of Ionizing Radiations, Time for Reassessment." The conclusion of the Phase I Scoping Committee was that information has become available since 1990 that makes this an opportune time to proceed with a BEIR VII Phase II study—"A Comprehensive Re-analysis of Health Risks Associated With Low Levels of Ionizing Radiations." The Phase I Scoping Committee provided a fivefold justification for its conclusion, namely --

- 1. There is a significant amount of new epidemiologic evidence, which includes the Radiation Effects Research Foundation data from Japan and the three-country nuclear worker study.
- 2. There is new data on cancer mortality for those who were exposed to whole-body irradiation in childhood.
- 3. There are useful studies of carcinogenesis that are focused on mechanisms and the cellular and molecular events that are involved in the neoplastic process.
- 4. The new information on biology now available in the current published literature should be evaluated, specifically, the use of knockout mice in genetic studies to determine susceptible subpopulations.
- 5. There is an increasing accumulation of evidence regarding specific biologic events that can affect the shape of the dose response curve at low doses.

Dr. Douple discussed the recommendations provided by the Phase I Scoping Committee for the implementation of its fivefold justification.

He stressed that the Phase I Scoping Committee was directed to look at the data in a manner that would provide information that could be used for risk assessment. He further stated that to assess the current status and relevance to risk models of biologic data, there are those who believe that they have to be able to model the Hiroshima and Nagasaki data. He suggested that those modelers might produce a risk analysis that may be very important and certainly one that could not have been performed 10 years ago.

Dr. Douple then summarized the types of epidemiologic data that have now become available since the BEIR V report was published. Among the studies to which he referred were the non-leukemia cancer mortality data that the Radiation Effects Research Foundation group published in 1996; the mortality data on a British series of patients treated with x-rays for ankylosis spondylitis (which was updated a few years ago); and the radiation worker studies, specifically those that have been coordinated in Europe by Elizabeth Cardis and others, and in

this country by Ethel Gilbert and others. He stated that there are new data for a variety of different cancer types, and that there are also data on radiation-related risk in patients known to be genetically susceptible to cancer.

He concluded his presentation by reiterating that the Phase II Reassessment Committee could develop a generalized strategy for risk modeling and illustrate it with specific examples. He stressed that the models should provide a good fit to the empirical epidemiologic data, be biologically plausible, be readily understood by the scientific community in general (favoring simple rather than complex models), and finally, should take into account all the relevant epidemiologic and biologic data.

The goal of the Phase II Reassessment Committee is to consider all data and information available since the 1990 BEIR V study and to conduct a comprehensive reassessment of health risks resulting from exposure to low levels of low linear energy transfer (LET) ionizing radiation. The timeline for this study is 3 years. Among the data to be evaluated are the A-bomb survivor data, medically irradiated cohorts, the former Soviet Union data as they become available—including data from studies of both Chernobyl and Chelyabinsk, nuclear workers, airline flight crews, and other studies. All information-gathering will be performed in public.

Dr. Douple then responded to several questions and comments concerning how specific biologic events could affect the shape of the dose response curve; the inclusion of information about radiation exposure from internally deposited radionuclides, including low LET radionuclides; and the use of the phrase "consensus report" as applied to this type of report versus an industry standard.

Dr. Edward Calabrese, Professor, University of Massachusetts, discussed the NMSS-funded hormesis database in his presentation titled "The Development of a Database on the Effects of Low Doses of Ionizing Radiation and Its Application for Assessing Radiation Hormesis as a Biological Hypothesis." He discussed chemical hormesis and the potential beneficial effects of low radiation exposure. Although there are known beneficial effects associated with exposure to low doses of certain poisons and radiation, it is not clear whether the risk of radiation-induced cancer is reduced in a beneficial way by low doses of ionizing radiation. Upon conclusion of his presentation, Dr. Calabrese responded to several questions and comments concerning quality assurance, NOEL (no observable effects level), and whether hormetic effects could be applied specifically to carcinogens.

Mr. Charles Meinhold, Vice Chairman of the International Commission on Radiological Protection (ICRP), discussed the ICRP's stance with respect to the issue of the LNT hypothesis (use if estimated risks are present using LNT models based on the atomic bomb survivor data). He mentioned the issue of persons who may be especially sensitive to exposure to ionizing radiation because of "sensitivity" genes that they might have inherited, suggesting that these persons might represent a significant fraction of the population. Mr. Meinhold pointed out that the ICRP makes use of the word "nominal" and that this designation reflects the difference

between the occupationally exposed worker population and the general public, the latter including young people who are considered to be more sensitive to radiation exposure.

He noted that in 1997, the ICRP put together a task group to examine the LNT issue. This task group reviewed the data in a process very similar to that used by the NCRP's SC 1-6. Mr. Meinhold discussed the differences in ICRP Publication 26 and ICRP Publication 60 regarding risk and tissue weighting factors. He stated that an error could be made if the ICRP Publication 26 risk factor was used with the ICRP Publication 60 tissue weighting factors.

Upon conclusion of his presentation, Mr. Meinhold, who represented both the ICRP as well as the NCRP, responded to several questions and comments concerning the number of deaths from cancer using the risk factors in ICRP Publication 60, and the credibility of the NCRP and the acceptance of its reports.

Dr. Myron Pollycove, NMSS, who has addressed the Committee on his perspectives on the LNT hypothesis at past working group meetings on this topic, presented his comments on the NCRP SC 1-6 draft report. He stated that although he seconded Dr. Otto Raabe's sentiment that Dr. Upton presented a very balanced presentation, he believed that the tenor of the draft written report did not seem as objective and balanced as Dr. Upton's presentation. He characterized the draft report as an effort to defend the LNT hypothesis and to discount anything that contradicts it. He perceives the report as having a flavor that is defensive and very protective of the position that has been maintained since 1959—the year the ICRP first adopted the hypothesis— proposed by United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) in 1958. He read excerpts from the ACNW letter of July 16, 1996, to the Commission, in which the ACNW recommended that an independent entity with expertise in statistics or information science, but no prior position on LNT, evaluate all of the data. He does not believe that that recommendation was carried out.

Dr. Pollycove noted that in some studies cancer rates are actually lower than baseline levels for low-dose groups. He stated that the assumption of linearity for radiation-induced cancer often leads to the rejection of studies that do not show linearity as being somehow faulty. (LNT has become a paradigm, and the standard of acceptance of information that does not fit the LNT paradigm is higher than that that does. This means that it can often be harder to publish studies that tend to put the LNT hypothesis in question, and those that are studied are likely to be given less consideration by consensus committees—such as SC 1-6 and BEIR VII.) He also suggested that there may be biases that are built into radiobiological research focused on radiation damage to cellular DNA, some types of which may occur in proportion to dose, thereby suggesting an LNT model. However, cells are normally subjected to considerable DNA damage associated with endogenous processes, and the body responds to these effects in protective ways. Such compensation to radiation exposure might be expected to lead to greatly reduced risk than calculated risk using the LNT. The stimulatory effects of radiation exposure might lead to lower than normal risks, that is, beneficial effects.

Upon conclusion of his presentation, Dr. Pollycove responded to comments and questions concerning his remarks.

Mr. Keith Dinger, President of the Health Physics Society (HPS), presented the HPS's policy on funding ionizing radiation health effects studies. He stated that the policy reflected the views of the HPS's policymakers and spokespersons on the issue of funding and research for ionizing radiation health effects and does not, therefore, necessarily represent the views of all the members of the society. This policy, which is intended to provide the advice of the HPS on the judicious expenditure of public money for the purpose of improving public health, was developed after HPS learned of DOE's low-dose research program.

Mr. Dinger then discussed the six recommendations of the policy, noting that the HPS is concerned about the usefulness of small and incomplete epidemiological studies that do not or cannot evaluate the full range of confounding factors. In the HPS position statement "Radiation Risk in Perspective," the HPS "recommends against quantitative estimation of health risks below an individual dose of 5 rem in one year or a lifetime dose of 10 rem in addition to background radiation." It further states that "risk estimation in this dose range should be strictly qualitative accentuating a range of hypothetical health outcomes with an emphasis on the likely possibility of zero adverse health effects." In its position statement on "Radiation Standards for Site Cleanup and Restoration," the HPS defends the inherent safety associated with annual exposures of the general public to doses smaller than 100 mrem above background. Mr. Ted Quinn, President of the American Nuclear Society, indicated agreement with these positions.

Mr. Dinger responded to comments and questions. Among those discussed were whether the HPS had a position statement on the Yucca Mountain standard, the funding of epidemiological studies that cannot improve the knowledge of the risk estimate or of the biological response at low doses, and the HPS's "Radiation Risk in Perspective" position statement.

Mr. Ray Johnson, President-elect of the HPS, emphasized the importance of improved risk communication with the public, stating that the public reacts to the images that they have of the dire consequences widely associated with radiation exposures. The industry needs improved risk communication to address people's fears, perceptions, and beliefs.

Panel Discussion

Following the presentations, a panel discussion was held. At this time, the panel members gave their observations of the day's presentations:

- 1. The key issues were put forth.
- 2. Scientific work related to the LNT hypothesis is underway. The results of those efforts must be communicated in an effective and transparent manner.
- 3. The question of an adaptive response and hormesis should be addressed and may influence the final model.
- 4. Without the ability to communicate well, the impact of good science can be lessened—or lost.
- 5. The HPS representatives requested reasonableness in NRC radiation protection regulations.
- 6. The EPA panel member emphasized the need to consider public acceptance when determining cost benefits and allocating resources.
- 7. The member of the panel from the Nuclear Energy Institute stated that he realized that the linear model simplifies dose management, but what is missing is the establishment of some reasonable lower bound. He suggested that perhaps research could establish one. He also noted that such a bound was also important to the NRC as it proceeds towards the establishment of clearance levels.
- 8. Although LNT can be considered a scientific problem, one panel member observed that the problem is more societal, being one that requires a decision as to what constitutes "good" as well as what constitutes "bad" public policy.

Before concluding the first day, Mr. Rockwell, Radiation Science and Health, Inc., presented information and data that suggested that low doses and dose rates not only do not pose linear proportional risks of cancer or mortality, but in fact, may lead to lower-than-normal cancer rates. In particular, he discussed the nuclear shipyard study in which radiation workers were compared to other workers in the same facility. The report indicated that radiation workers had much lower death rates than the non-radiation workers. Mr. Rockwell opined that these, as well as other data that show similar phenomena, need to be addressed and answered so as to make a small presentation on the nuclear shipyard worker study. He stated that he would like the NCRP to look at the data on LNT that his group has compiled.

ACNW members were given an opportunity to ask questions of the panel members concerning their presentations and things that they had observed over the course of the day so that they could begin to organize their thoughts for a subsequent letter to the Commission.

On the second day of the meeting, Messrs. T. Rockwell and James Muckerheide, both representing Radiation Safety and Health, Inc., addressed the Committee. Mr. Rockwell expressed his concern about the failure of the NCRP SC 1-6 draft report to address "all" of the available data pertaining to the LNT hypothesis. These concerns were seconded by Mr. Muckerheide. Mr. Muckerheide referred to studies that ostensibly were included in the NCRP SC 1-6 draft report but noted that portions of these studies that discussed hormetic response were ignored. He also expressed concern that one study was being ignored—and even panned—as being an anomaly and the result of one man's extraordinary treatment of the data.

Mr. Muckerheide was asked if he thought that a threshold existed and what that threshold might be. He stated that the threshold might be on the order of about 10 to 20 rem. He also responded to comments and questions concerning DOE's low-dose research program, and whether there was a group that he believed would give reasonable consideration to the total database of merit.

Mr. Quinn of the American Nuclear Society (ANS), stated that the ANS is developing its own public policy statement on the issue of the effects of low-level radiation which should be issued in mid-April 1999

Dr. Myron Pollycove pointed out what he considered to be flaws in the reasoning concerning LNT and low-dose health effects. Dr. Pollycove stated that he thought one of the Committee's recommendations to the Commission should be that because of the biases he perceived in the NCRP report, perhaps another, more independent panel should be constituted, which would then prepare another, more balanced report.

Drs. Kearfott and Raabe, consultants to ACNW for this working group meeting, presented their impressions of the meeting and their recommendations for the ACNW. Dr. Raabe pointed out that protracted exposures from internally deposited radionuclides is not being considered by the NCRP, the BEIR VII effort, or the DOE program. He also pointed out that the LNT question has two parts, linear and non-threshold, and that some people associate "non-threshold" with zero risk. Dr. Kearfott stated that from her perspective, there are three principal problems associated with this issue, to wit: credibility, certainty, and creativity. She then elaborated upon each of these points.

Subsequent to the meeting, the ACNW received letters from Mr. Muckerheide of Radiation, Science, and Health, Inc. and Mr. A. David Rossin of the Center for International Security and Cooperation at Stanford.

III. PROGRESS OF A CLEARANCE RULE FOR MATERIALS AND EQUIPMENT HAVING RESIDUAL RADIOACTIVE CONTAMINATION (OPEN)

[Howard J. Larson was the Designated Federal Official for this portion of the meeting.]

Messrs. F. Cardile and T. Huffert, NMSS, presented an update on the status of the staff's current development efforts on the clearance rulemaking. They noted that the Commission, in its staff requirements memorandum (SRM) of June 30, 1998, had directed the staff to proceed with the promulgation of a dose-based rule on clearance and to begin using an enhanced participatory rulemaking process in Fiscal Year 1999.

After presenting a brief history and background of the proposed rule, Messrs. Cardile and Huffert discussed the following:

- 1. The four facilitated public hearings currently scheduled for different geographical locations (Chicago, Atlanta, San Francisco, and Washington, D.C.) between August and November 1999.
- 2. The rationale for considering a rulemaking, potential alternative courses of action, previous Commission efforts to address the release of solid materials [viz., the July 1991 proposed below regulatory concern (BRC) policy], and the following four principal issues (and potential options) to be discussed in the issues paper (currently scheduled to be released in April 1999):
 - a. Should the NRC address inconsistency in its release standards by conducting a rulemaking on release of solid materials?
 - b. If the NRC decides to develop a proposed rule, what are the principal alternatives for rulemaking that should be considered?
 - c. If the NRC decides to develop a proposed rule, could some form of restrictions on future use be considered as an alternate?
 - d. If the NRC decides to develop a proposed rule, what materials should be covered?
- 3. The direction provided by the Commission in the development of the technical basis document. In addition to being dose based, the SRM stated that the staff was to -
 - a. Focus on clearance levels above background for unrestricted use.

- b. Draw from International Atomic Energy Agency reports (1 mrem/year), current contractor analyses, and current naturally occurring or naturally accelerator-produced radioactive material practices.
- c. Base the standard on realistic scenarios.
- d. Develop a comprehensive standard (metals, equipment and materials, including soil).
- e. Draft a report of individual dose factors for clearance (some 79 scenarios were analyzed).
- f. Additionally plan to develop an individual dose assessment for soils, a collective dose assessment, and a cost-benefit analysis.
- g. Build on the progress made by EPA in developing a technical basis.
- h. Develop a generic environmental impact statement, a regulatory analysis, and a regulatory guide for implementation guidance. (Statements of work are being developed to assist in the preparation of these documents.)

In response to a question, the staff indicated that its most difficult challenge will be the justification for, and the establishment of, the clearance level value. The Committee indicated an interest as to how the cutoff value would be determined and how that value was allocated from the 100-mrem/year starting point. It was also stated that the value would not be based on a specific isotope.

Among other questions asked by the Committee that resulted in significant interactions was the use of the collective dose concept as applied to the definition and application of the clearance rule. The Committee suggested that the agency's risk-informed, performance-based regulation philosophy should also apply to the clearance rule.

The Committee indicated that it had a continuing interest in the proposed rule, intended to follow its progress closely, and would appreciate receiving an update as to the proposed rule before its submission to the Commission in February 2000.

IV. PROGRESS IN THE DEVELOPMENT OF THE DECOMMISSIONING STANDARD REVIEW PLAN (OPEN)

[Howard J. Larson was the Designated Federal Official for this portion of the meeting.]

Mr. Nick Orlando, NMSS, updated the Committee on the current status of the subject plan. He was assisted in responding to questions from members by Dr. R. Abu-Eid and Messrs. R. A. Nelson and M. Thaggard.

In his introductory remarks, Mr. Orlando noted that despite the loss of several key staff members, the development of the standard review plan (SRP) on decommissioning was still proceeding on the schedule originally envisioned. After providing a brief review of the direction given to the staff in the Commission's SRM dated July 7, 1998, Mr. Orlando discussed the following:

- 1. The staff SRP development progress to date (the timely establishment of SRP module workgroups, the publishing of default values to replace Regulatory Guide 1.86, and the identification of technical and policy issues requiring resolution).
- 2. Topics presented and inputs received thus far from the three public stakeholder meetings held in the NRC Two White Flint North auditorium in December 1998, January 1999, and March 1999. He noted that the major focus areas during these workshops were dose modeling, the as low as reasonably achievable (ALARA) principle, and the concept of restricted release. Additional stakeholder meetings addressing ground water modeling, DandD code screening, surveys, and Agreement States issues are scheduled for June, August, and October 1999.
- 3. Future SRP development milestone dates. The public comment period is scheduled to close August 1999; revisions to the SRP on the basis of those comments are to be completed by May 2000 and the final SRP published in July 2000.
- 4. The remaining issues requiring resolution. Issues identified were restricted use/alternate criteria, dose modeling, ALARA, health and safety (H&S) plans, surveys, and the financial assurance requirements.

In response to a question from the Committee as to the most difficult issue, Mr. Orlando indicated that he believed resolution of the dose modeling issue presented the greatest challenge, whereas for the H&S and financial assurance issues, the answers appeared to be rather straightforward.

Of particular interest to the Committee was the development of both the DandD and RESRAD codes and the anticipated stakeholder acceptance (or difficulty) with that approach. Also of

interest were the discussions on partial site release and the problems associated with such a concept.

In response to a question from Dr. Garrick as to the efficacy of the workshops, Mr. Orlando summarized his evaluation as follows:

- 1. Industry seemed appreciative that the NRC was interacting with it before issuance of the SRP.
- 2. Industry was very interested in the concept of partial release of a site, believing that the relatively prompt release of large areas of uncontaminated land inside the site boundary could greatly reduce costs insofar as monitoring, surveys, and so on are concerned.
- 3. Since the license termination rule was new, utilities not only had to become familiar with the rule but also raised questions about the finality of the license termination decisions.
- 4. In the interest of mutual cooperation, licensees have brought in actual recent survey data that were previously not available to the staff. This step has been of much assistance to the staff insofar as to updating its database is concerned. (Until this exchange, the staff had been using 1963-64 data.)

The Committee expressed its appreciation for the update and was looking forward to another status report once the public workshops and comment period were over. The staff indicated its willingness to schedule such a review in the fall of 1999.

V. EXECUTIVE SESSION (Open)

[Mr. Richard Major was the Designated Federal Official for this part of the meeting.]

A. Future Meeting Agenda (Open)

Appendix IV summarizes the proposed items endorsed by the Committee for the 109th ACNW meeting on May 11–13, 1999.

B. <u>Future Committee Activities</u> (Open)

The 110th ACNW meeting is scheduled for June 28–30, 1999, at the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas.

APPENDIX III: MEETING ATTENDEES

108TH ACNW MEETING MARCH 23–25, 1999

ACNW STAFF

Dr. Andrew Campbell

Ms. Lynn Deering

Ms. Michele Kelton

Dr. John Larkins

Mr. Howard Larson

Dr. Richard Savio

Ms. Mary Thomas

ATTENDEES FROM THE NUCLEAR REGULATORY COMMISSION

MARCH 23, 1999

ACRS N. Dudley M. Pollycove **NMSS** P. Castleman **OEDO** S. Yaniv RES RES C. Trottier **RES** P. Reed S. Crockett OCM/EXM I. AL-Nabulsi NAS/NRC

R. Jostes NAS/NRC E. Douple NAS/NRC

MARCH 24, 1999

K. Shimomura RES S. Yaniv RES

P. Castleman OCM/NJD
M. Pollycove NMSS
G. Gnugnoli NMSS
P. Holahan NMSS

B. Abu-Eid NMSS E. Brummell NMSS

B. Nelson NMSS
T. Huffert NMSS

Appendix III 108th ACNW Meeting March 23-25, 1999

ATTENDEES FROM OTHER AGENCIES AND GENERAL PUBLIC

MARCH 23, 1999

B. Mills Health Physics Society
R. Johnson Health Physics Society

C. Nelson EPA
A. Clamp NEI
R. Wallace USGS/HQ
G. Roseboom USGS/Retired

J. Puskin EPA

W. Donald McCarter & English

J. Muckerheide Radiation Science & Health T. Rockwell Radiation Science & Health K. Dinger Health Physics Society

A. Upton NCRP
C. Meinhold NCRP/ICRP
M. Fraizer DOE
L. Ralston EPA

R. Shaw McCarter & English

L. Bissell Booz Allen S. Crawford Consultant

T. Fabian Nuclear Waste News

R. Godfrey ANSTO/Embassy of Australia

R. Maiers PA/DEP-BRP

D. Thomassen DOE

MARCH 24, 1999

D. Kopsick EPA
R. Wallace USGS
T. Rockwell RSH
J. Muckerheide RSH
R. Maiers PA/DEP
K. Dinger HPS
E. Quinn ANS

R. Godfrey ANSTO/EMB of Australia

L. Bissell Booz Allen/DOE

L. Muckerheide Radiation Science & Health

Japan Nuclear Cycle Dev. Inst.

APPENDIX IV: FUTURE AGENDA

The Committee agreed to consider the following during the 109th ACNW Meeting, May 11-13, 1999:

- <u>ACNW Planning and Procedures</u> The Committee will hear a briefing from ACNW staff on issues to be covered during this meeting. The Committee will also consider topics proposed for consideration by the full Committee and working groups. The Committee will discuss ACNW-related activities of individual members.
- Risk Communications The Committee will begin to prepare for a working group
 meeting scheduled for October on this topic with a number of lead-in presentations.
 Presentations are anticipated with people representing other government agencies and
 private industry and on risk communication initiatives underway at NRC.
- <u>Yucca Mountain Review Plan</u> The NRC staff will discuss the strategy for converting the Issue Resolution Status Reports for the proposed high-level waste repository at Yucca Mountain into a review plan for the repository license application.
- Meeting With NRC's Executive Director for Operations (EDO) The Committee will
 meet with the EDO to discuss items of mutual interest.
- <u>Preparation of ACNW Reports</u> The Committee will discuss planned reports, including reports on biological effects of low levels of ionizing radiation, a white paper on repository design issues at Yucca Mountain, and other topics discussed at this and previous meetings.
- <u>Miscellaneous</u> The Committee will discuss miscellaneous matters related to the
 conduct of Committee activities and organizational activities and complete discussion of
 matters and specific issues that were not completed during previous meetings, as time
 and availability of information permit.

APPENDIX V LIST OF DOCUMENTS PROVIDED TO THE COMMITTEE

[Note: Some documents listed below may have been provided or prepared for Committee use only. These documents must be reviewed prior to release to the public.]

MEETING HANDOUTS

AGEN	<u>IDA</u>
ITEM	NO.

DOCUMENTS

2 <u>Low-Levels of Ionizing Radiation</u>

- 1. **Viewgraphs** presented by Dr. Arthur Upton, Chairman, National Council on Radiation Protection and Measurements Scientific Committee 1-6
- 2. The Linear-Nonthreshold Dose-Response Model: A Critical Reappraisal, paper by Arthur C. Upton, M.D., University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, Piscataway, New Jersey, presented at the 35th Annual Meeting of the National Council on Radiation Protection and Measurements, 1999 [Handout]
- DOE Low Dose Radiation Research Program, presented by Dr. Marvin Frazier, Office of Science, Office of Environmental Management, [Viewgraphs]
- 4. **Viewgraphs** presented by Charles, Land, Radiation Epidemiology Branch. National Cancer Institute
- Viewgraphs on the development of a data base on the effects of low doses of ionizing radiation and its application for assessing radiation hormesis as a biological hypothesis, presented by Dr. Edward J. Calabrese, University of Massachusetts
- 6. ICRP and the LNT, presented by Charles B. Meinhold, President, NCRP, Vice Chairman, ICRP, [Viewgraphs]
- 7. A White Paper, Thoughts on the Adoption of ICRP Publication 27 Concepts and the Juxtaposition of the Adoption of ICRP Publication 60 Risk Estimates, Charles B. Meinhold, Safeguards, Safety, and Nonproliferation Division, Department of Advanced Technology, Brookhaven National Laboratory [Handout]
- 8. The Nuclear Shipyard Workers Study, by Theodore Rockwell, VP, Radiation, Science & Health, Inc. [Viewgraphs]
- 9. The Urgent Need to Revise Radiation Protection Policy, Testimony Before the Advisory Committee on Nuclear Waste of the NRC, Theodore Rockwell, VP, Radiation, Science & Health, Inc., dated March 23, 1999 [Handout]
- 10. Excepts form Draft RSH Report, Section 2.0, Conclusions on the LNT: Science, Data, Policies, and Corrective Actions, dated March 18, 1999 [Handout]
- 11. **Viewgraphs** presented by Myron Pollycove, Office of Nuclear Material Safety and Safeguards, NRC

Appendix V 108th ACNW Meeting March 23-25, 1999

MEETING HANDOUTS (CONT'D)

AGENDA ITEM NO.

DOCUMENTS

2 Low-Levels of Ionizing Radiation (Cont'd)

- 12. The Health Physics Society Policy on Expenditure of Funds for Ionizing Radiation Health Effects Studies, Remarks to the Advisory Committee on Nuclear Waste, by Keith H. Dinger, CHP, President, Health Physics Society [Viewgraphs]
- 13. Health Physics Society Information for the Nuclear Regulatory Commission's Advisory Committee on Nuclear Waste, In support of the "Working Group" Meeting on the "Linear Non-Threshold Hypothesis," by Keith H. Dinger, MS, CHP, President, Health Physics Society (with attachments) [Handout]

5 Clearance Rule

14. Briefing for Advisory Committee on Nuclear Waste, On the Status of Clearance Rulemaking, presented by Frank Cardile, NMSS, dated March 24, 1999 [Viewgraphs]

6 Standard Review Plan for Decommissioning

- 15. Update of NRC's Plans to Develop a Standard Review Plan for Evaluating Decommissioning Plans and Other Information Submitted to Support the Decommissioning of Nuclear Facilities, presented by Dominick Orlando, NMSS, dated March 24, 1999
- 16. Issues Requiring Resolution to Develop a Decommissioning SRP, provided by Dominick Orlando, NMSS [Handout]

9 Preparation of ACNW Reports

9.1 DOE's Viability Assessment

17. Letter from Michael Bell, NMSS, to Stephan Brocoum, DOE, Subject: Importance Analysis, dated March 2, 1999 [Handout 1, Agenda Item 9.1]

Appendix V 108th ACNW Meeting March 23-25, 1999

MEETING NOTEBOOK CONTENTS

<u>TAB</u> NUMBER

DOCUMENTS

Opening Remarks by ACNW Chairman

- 1. Schedule and Outline for Discussion, 108th ACNW Meeting, March 23–25, 1999, dated March 22, 1999
- 2. Introductory Statement by the ACNW Chairman, undated
- 3. Introductory Statement by the ACNW Chairman, Second Day, undated
- 4. Introductory Statement by the ACNW Chairman, Third Day, undated

2 <u>Low Levels of Ionizing Radiation</u>

- 5. Status Report
- 6. Task Action
- 7. Letter dated July 10, 1996, from Paul W. Pomeroy, Chairman, ACNW, to The Honorable Shirley Ann Jackson, Chairman, NRC, Subject: Health Effects of Low Levels of Ionizing Radiation
- 8. Letter dated August 9, 1996, from James M. Taylor, EDO, to Paul W. Pomeroy, Chairman, ACNW, Subject: Health Effects of Low Levels of Ionizing Radiation
- 9. Memorandum dated October 16, 1997, from Commissioner Nils J. Diaz, NRC, to Dr. B. John Garrick, Chairman, ACNW, Subject: Health Effects of Low-Level Ionizing Radiation
- 10. Memorandum dated December 2, 1997, from B. John Garrick, Chairman, ACNW, to Commissioner Nils J. Diaz, NRC, Subject: Health Effects of Low-Level Ionizing Radiation
- 11. NCRP Draft Report SC 1-6, "Evaluation of the Linear Nonthreshold Dose-Response Mode, dated October 1998
- 12. NCRP. Background Information
- 13. "Research Program Plan, 'Biological Effects of Low Dose and Dose Rate Radiation,'" Prepared for: The Office of Biological and Environmental Research, by The Low Dose Radiation Research Program Plan Subcommittee of the Biological and Environmental Research Advisory Committee. **Draft Document**
- 14. Department of Energy Charter, Biological and Environmental Research Advisory Committee
- 15. Biological and Environmental Research Advisory Committee, Membership List

MEETING NOTEBOOK CONTENTS (CONT'D)

<u>TAB</u> NUMBER

DOCUMENTS

- 16. "Health Effects of Exposure to Low Levels of Ionizing Radiations, Time for Reassessment?" Committee on Health Effects of Exposure of Low Levels of Ionizing Radiations (BEIR VII), Board on Radiation Effects Research, Commission on Life Sciences, National Research Council
- 17. Health Physics Society Policy on Expenditure of Funds for Ionizing Radiation Health Effects Studies
- 18. Developments in Radiation Health Science and Their Impact on Radiation Protection, OECD Nuclear Energy Agency, Committee on Radiation Protection and Public Health, Report of the Working Group on Science and Technology Affecting Radiation Protection Sub-Group on Radiation Health Sciences (WGST-RHS)
- 19. Press Release, Council of Scientific Society Presidents, "Experts Agree for First Time That Radiation Exposure Above 10,000 Millirem Produced Significantly Increased Risk of Cancer in Adults, Final Report, Wingspread Conference, "Creating a Strategy for Science-Based National Policy: Addressing Conflicting Views on the Health Risks of Low-Level Ionizing Radiation," Council of Scientific Society Presidents, dated March 3, 1998

5 <u>Meeting With the Director of the Division of Waste Management</u>

20. Status Report

6 Rulemaking Process for Clearance of Materials

- 21. Status Report
- 22. Memorandum from dated March 1, 1999, from H. J. Larson, ACNW, to ACNW Members, Subject: SECY-99-028, "Rulemaking Process in Response to The Staff Requirements Memorandum for SECY-98-028," "Regulatory Options for Setting Standards on Clearance of Materials and Equipment Having Residual Radioactivity," January 27, 1999

8 <u>Development of a Standard Review Plan for Decommissioning</u>

23. Status Report

Appendix V 108th ACNW Meeting March 23-25, 1999

MEETING NOTEBOOK CONTENTS (CONT'D)

<u>TAB</u> NUMBER	DOCUMENTS
24	4. Memorandum from John C. Hoyle, Secretary, NRC, to L. Joseph Callan, EDO, Subject: Staff Requirements - SECY-98-051 - Guidance in Support of Final Rule on Radiological Criteria for License Termination
29	5. Letter dated January 11, 1999, from B. John Garrick, Chairman, ACNW, to The Honorable Shirley Ann Jackson, Chairman, NRC, Subject: Development of a Standard Review Plan for Decommissioning
20	Letter dated February 23, 1999, from William D. Travers, EDO, to Dr. B. John Garrick, Chairman, ACNW, Subject: Development of a Standard Review Plan for Decommissioning
2.	7. NMSS Decommissioning Program, Standard Review Plan 1.0, Executive Summary, dated February 25, 1999
28	3. Final Agenda, Public Workshop on Guidance for Implementing 10 CFR 20, Subpart E, Radiological Criteria for License Termination
29	P. Viewgraphs (Draft), Update of NRC's Plans to Develop a Standard Review Plan for Evaluating Decommissioning Plans and Other Information Submitted to Support the Decommissioning of Nuclear Facilities, Presentation to the ACNW, March 24, 199, Contact: Dominick A. Orlando
10 <u>C</u>	ommittee Activities/Future Agenda

- 30. Set Agenda for 109th ACNW Meeting, May 11-13, 1999
- 31. Agenda for Out Months through October 1999
- 32. ACNW/ACRS Meeting Calendar for April-December, 1999
- 33. Executive Director for Operations' List of Future Meeting Topics
- 34. Civilian Radioactive Waste Management Office M&O Meeting List, March 8, 1999

11 <u>Preparation of ACNW Reports</u>

35. **Revised** Final Comparison of Proposed 10 CFR 63 and Existing 10 CFR 60