

Activities Associated with Evaluating Scientific Information and Radiation Protection Recommendations

Title: Radiation Effects Research Foundation

Background/Context:

The Radiation Effects Research Foundation (RERF) is a private, nonprofit organization (supported by the governments of Japan and the United States), which conducts scientific research to study the health effects of radiation exposure on the atomic bomb survivors from Hiroshima and Nagasaki. As such, RERF established several study groups to provide epidemiological and clinical data on the health status and eventual mortality of the survivors and their children. Specifically, RERF conducts research studies in the fields of radiobiology, immunology, genetics, and molecular epidemiology to help interpret the findings and promote an understanding of the mechanisms of disease induction. Among those studies, RERF recently reassessed and revised the radiation dosimetry system (DS) used to estimate the radiation dose to the survivors. RERF published DS02 and made the updated report available on its Web site. It is also expected to update its related cancer risk estimates, which provide a major basis for estimating radiation-induced health effects.

Desired Outcome:

Careful analysis of the cancer incidence and cancer mortality data for the atomic bomb survivors should yield fundamental health and risk information for radiation protection standards worldwide. RERF will also use the updated DS to reevaluate its radiation risk assessments for cancer incidence and cancer mortality among the atomic bomb survivors. Preliminary data were reviewed by the National Academy of Sciences BEIR VII committee and final published data will be used by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

Activities:

Japanese and U.S. investigators reassessed and revised the radiation exposures assigned to the Japanese atomic bomb survivors from Hiroshima and Nagasaki. The revisions included adjusting the bomb yields, burst heights, and orientation at the time of detonation, as well as the impact of shielding (e.g., trees, buildings, furniture) on individual radiation dose estimates. These revisions had a less-than-anticipated impact on the radiation dose assigned to each survivor, with the primary change consisting of an increase of about 10 percent in the estimated gamma-ray exposure for both Hiroshima and Nagasaki survivors. This increase, in turn, decreased the radiation-induced cancer risk estimates for solid cancer (e.g., breast cancer) and leukemia by about 8 percent although the apparent shape of the dose response curve remains virtually unchanged. RERF investigators believe these changes will substantially improve the analysis of data concerning children born to atomic bomb survivors.

Plans for Interaction and Evaluation:

The National Academies and the International Commission on Radiological Protection have reviewed new cancer incidence data for the atomic bomb survivors. These data have not yet been published in a peer-reviewed journal.

Enclosure

During normal day-to-day activities (such as review of published open literature on RERF; robust website, attendance of various related conferences, participation in both RERF activities and those sponsored by UNSCEAR, etc.); the staff plans to continue to monitor the research published out of RERF, including the review and assessment of cancer and non-cancer disease among survivors. In particular, the staff will monitor radiation-induced cataract formation and determine if ocular radiation protection standards are adequately protective. In addition, the cancer mortality coefficients will be revised, if appropriate, based on the new Japanese data. Staff will review these reports and evaluate their impact on NRC's radiation protection regulations.

Title: U.S. Department of Energy Low Dose Radiation Research Program

Background/Context:

In 1998, Congress asked the U.S. Department of Energy (DOE) to initiate a basic research program to establish risk assessment standards for cancer mortality and morbidity based on a strong scientific foundation. In response, the DOE Office of Biological and Environmental Research initiated a 10-year basic research program in 1999 (at a projected cost of \$20 million per year) to determine the health risks attributable to exposures to low levels (10 rad and below) of ionizing radiation.

Desired Outcome:

This research program will generate data that should improve understanding of the health effects attributable to exposure to low-level ionizing radiation. DOE intends to use the data to evaluate models that predict human health risks and determine whether radiation protection standards warrant any changes. In particular, it would be useful to ascertain the dose response curve for human health effects of exposures below 100 millirem (1 millisievert), which remain well below the limit of detection for the biological techniques currently used by DOE investigators.

Activities:

Currently, DOE funding for this program is focused on understanding: (1) how radiation (natural background and man-made radiation sources) damages DNA and how the cell responds by repairing this damage; (2) how radiation-induced DNA damage differs from day-to-day damage induced by cellular metabolism; (3) how cells respond or adapt when repeatedly exposed to radiation; (4) how irradiation of a single cell impacts those cells surrounding it (bystander effects); and (5) whether there is a genetic basis for individual differences in sensitivity to radiation exposure. To date, DOE has reported a significant increase in new techniques and instrumentation for use in measuring the biological and genetic changes induced by exposure to low doses of radiation. Detailed information appears at <http://www.lowdose.energy.gov/index.htm> and includes a list of the funded projects, abstracts of past research, published scientific papers, and past and future directions of the program.

Plans for Interaction and Evaluation:

Every 18 months, DOE hosts a Low Dose Radiation Research Program Investigators' Workshop to review and discuss the scientific results of each funded project. DOE held the sixth workshop July 30–August 2, 2006, in Washington, DC. This workshop provided an opportunity for the program investigators to discuss successes, problems, and challenges in their research. Investigators from every project presented their current work in the poster sessions, and some gave platform presentations. U.S. Nuclear Regulatory Commission (NRC) staff from the Offices of Nuclear Regulatory Research (RES) and Nuclear Material Safety and Safeguards (now in the Office of Federal and State Materials and Environmental Programs) attended the workshop and discussed with the principal investigators the status of their research. The next workshop date, location, and time are to be determined.

Title: U.S. National Academies - Nuclear and Radiation Studies Board

Background/Context:

The mission of the National Academies' Nuclear and Radiation Studies Board is to provide an open forum for discussion and to organize and oversee studies on safety, security, technical efficacy, and other policy and societal issues arising from the application of nuclear and radiation-based technologies. Topics under the Board's purview include scientific studies that examine the health effects, consequences, and amelioration of exposure to ionizing and non-ionizing radiation, including periodic assessments of the biological effects of ionizing radiation, and the risks, benefits, and/or efficacies of nuclear and radiation-based technologies.

Desired Outcome:

NRC staff will monitor the work of the Nuclear and Radiation Studies Board, through attendance at meetings and symposiums to keep abreast of the latest studies on the biological effects of radiation exposure. The information obtained from the National Academies will be used as part of the technical basis for updating 10 CFR Part 20, "Standards For Protection Against Radiation."

Activities:

The Nuclear and Radiation Studies Board routinely hosts open sessions for researchers to present their work. In July 2006, staff attended the "Radiation Health Effects" session. Topics included, "estimates of cancer burden in Europe from radioactive fallout from the Chernobyl accident," "non-cancer health effects of ionizing radiation from studies of atomic bomb survivors," "non-cancer health effects from radiotherapy," and "an update on the future of the Radiation Effects Research Foundation."

Staff attended the Fifth Annual Gilbert W. Beebe Symposium on November 28, 2006. The theme of the symposium was Pre- and Post-conception Radiation Exposure: Sensitivity of Gametes, Fetuses, and Children. Topics included "An Overview of Pediatric Radiation Epidemiology;" "Thyroid Cancer in Radiation-Exposed Children;" "What We Can Learn About Risks of Exposure to Gametes, Fetuses, and Children from the Atomic Bomb Casualty Commission/RERF Studies;" "Long-Term Effects of Radiotherapy for Childhood Cancer;" and "Current Concepts in Radiation Genetics."

Plans for Interaction and Evaluation:

Staff will continue to monitor the activities of the Board and will attend applicable meetings and symposiums. The Sixth Annual Beebe symposium is scheduled for Fall 2007 in Washington D.C. The date and theme of the symposium are to be determined.

Title: United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

Background/Context:

The UNSCEAR charter is to assess and report levels and effects of exposure to ionizing radiation on humans and the environment. Toward that end, UNSCEAR meets annually and issues comprehensive reports every 2 to 5 years. Foreign governments and organizations rely on UNSCEAR evaluations as the scientific basis for estimating radiation risk, establishing radiation protection and safety standards, and regulating radiation sources. In fact, United Nations' agencies, such as the International Atomic Energy Agency (IAEA), use UNSCEAR reports exclusively as the technical basis for their recommendations and decisions. The work of UNSCEAR is also of significant interest to many U.S. agencies, including the NRC. For example, the staff used several annexes contained in the UNSCEAR 1988 report as part of the technical basis to justify the last major revision of its radiation protection standards. UNSCEAR published its most recent major report in 2000 and may publish the next report later this year.

Desired Outcome:

The next UNSCEAR report should provide a definitive assessment of health effects data and models of cancer induction, including a critical assessment of all data that might affect the shape of the dose response curve at low doses and evidence of thresholds (or lack thereof) in dose response relationships. The UNSCEAR report will be used as a primary technical basis for developing and revising radiation risk estimates in 10 CFR Part 20, "Standards For Protection Against Radiation."

Activities:

UNSCEAR held its 54th session in Vienna, Austria, on May 29–June 2, 2006. The Committee approved five documents for publication in 2006, titled, "Epidemiological Studies of Radiation and Cancer," "Epidemiological Evaluation and Dose Response of Diseases Other Than Cancer," "Non-targeted and Delayed Effects of Exposure to Ionizing Radiation," "Effects of Ionizing Radiation on the Immune System," and "Sources-to-effects Assessment for Radon in Homes and Workplaces." The Committee provided feedback on drafts of other documents that addressed topics including medical radiation exposures, exposures of workers and the public from various sources of radiation, exposures from radiation accidents, and effects of ionizing radiation on nonhuman biota.

Plans for Interaction and Evaluation:

The NRC staff will continue to directly support the U.S. delegation to UNSCEAR by reviewing draft documents as they become available and providing technical guidance to the delegation and the UNSCEAR secretariat during Committee deliberations. The current U.S. representative to UNSCEAR is Dr. Fred A. Mettler, Jr., of the University of New Mexico Medical School. Dr. E. Vincent Holahan of the NRC is a technical advisor to the U.S. delegation. The staff will also assess the impact (if any) of UNSCEAR documents, when they are published, on the technical basis supporting the NRC's rulemaking activities. Publication of these documents is dependent on funding from the United Nations Environmental Program and could occur in mid-2007.

The Committee will hold its 55th session in Vienna on May 21–25, 2007.

Title: International Commission on Radiological Protection General Radiation Protection Recommendations

Background/Context:

The International Commission on Radiological Protection (ICRP) was established to advance the science of radiological protection by developing recommendations and guidance on all aspects of protection against ionizing radiation. ICRP published the latest comprehensive revision of its recommendations in 1991 and now believes that sufficient new scientific data have been produced since 1990 to warrant a new set of recommendations. The current revision effort is intended to make the system of radiation protection more coherent and less confusing.

ICRP made a draft set of recommendations available for public review and comment on its Web site (<http://www.icrp.org>) in June 2004 and June 2006. It received numerous comments, including those from the NRC. In April 2005, ICRP made a set of draft technical foundation documents available for public review. NRC staff reviewed these documents and provided comments to the Commission in SECY-04-0223, "Request for Approval of Staff Comments on the 2005 Recommendations of the International Commission on Radiological Protection," dated November 26, 2004, and in SECY-06-0168, "Staff Comments on the Draft Recommendations of the International Commission on Radiological Protection," dated July 27, 2006.

Desired Outcome:

NRC participation is intended to influence the drafting and revision of the final ICRP recommendations to ensure that they are supported by a scientifically sound technical basis.

Activities:

In June 2006, ICRP made a revised draft of the recommendations available for public review and comment. The NRC staff submitted comments to ICRP (SECY-06-0168). The staff also worked with the Organisation for Economic Co-operation and Development's Nuclear Energy Agency, Committee on Radiation Protection and Public Health, through the Interagency Steering Committee on Radiation Standards to host the first North American Workshop on ICRP Recommendations. The workshop, held in Rockville, Maryland, August 28–29, 2006, included participants from a wide range of regulatory, professional, industry, and nongovernmental organizations from the U.S. and Canada. In January 2007, ICRP made available a revised draft of the recommendations that served as a status report, and the staff provided comments to ICRP (SECY-07-0036, "Staff Comments on the Draft Recommendations of the International Commission on Radiological Protection," dated February 22, 2007). ICRP approved the recommendations in March 2007 and plans to publish them in the Annals of ICRP.

Plans for Interaction and Evaluation:

The staff will continue to monitor ICRP activities, review documents as they become available, and provide technical advice directly to the various ICRP committees. The staff prepared and provided comments on the draft document on medical exposure in April 2007. Staff will review the final recommendations when published and evaluate the impact, if any, on NRC's radiation protection regulations.

Title: International Commission on Radiological Protection Environmental Protection Recommendations

Background/Context:

ICRP has established a new activity on protection of the environment to develop a radiation protection policy and create a framework of environmental protection based on ethical and philosophical principles. It published the outline for the framework as ICRP Publication 91, "PA Framework for Assessing the Impact of Ionizing Radiation on Non-Human Species," in 2003. The new framework, which the draft ICRP recommendations in 2004 also referenced, was intended to serve as a parallel approach to the protection of humans. It is also designed for use as a practical tool to help regulators with existing and future regulatory standards. An agreed-upon set of quantities and units, a set of reference dose models, reference dose-per-unit-intake (or unit exposure), and reference fauna and flora will be developed to serve as a basis for the more fundamental understanding and interpretation of the relationships between exposure and dose for a few clearly defined types of animals and plants.

The ICRP created a new Committee 5 for the protection of nonhuman organisms for the 2005–2009 term. It formed this committee specifically to pursue activities in the environmental protection arena. The new committee held its first meeting in Geneva, Switzerland, in September 2005 and its second meeting in Corvallis, Oregon, in August 2006.

Desired Outcome:

NRC participation in ICRP processes is intended to inform and influence the development of ICRP recommendations to ensure that they have a sound scientific basis, are consistent with U.S. policies, and promote the Commission view that a separate framework for radiological protection on non-human species is unnecessary.

Activities:

NRC staff attended the ICRP Committee 5 meeting public session in August 2006 to maintain awareness of plans and activities. The ICRP devoted a chapter to Protection of the Environment in both the 2006 and 2007 versions of the draft ICRP recommendations. In both instances the staff informed the ICRP that separate recommendations for protection of the environment are unnecessary and that the NRC opposes future development of separate standards for flora and fauna. This position was reiterated at both NEA-sponsored workshops on the draft ICRP recommendations attended by NRC staff.

Plans for Interaction and Evaluation:

The staff will review draft ICRP materials as they become available and plans to prepare and provide comments for Commission information.

Title: National Council on Radiation Protection and Measurements General Radiation Protection Recommendations

Background/Context:

The National Council on Radiation Protection and Measurements (NCRP) has been active in the areas of radiation protection and measurements since its inception as the Advisory Committee on X-Ray and Radium Protection in 1929. The NCRP charter states that its objectives are, in part, to collect, analyze, develop, and disseminate information and recommendations about radiation protection and radiation measurements, quantities, and units concerned with radiation protection. NCRP last issued general radiation protection recommendations in NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," issued in 1993. The NRC staff anticipates that NCRP will want to reiterate and update its position on radiation protection issues following the publication of additional data on the biological effects of ionizing radiation by the National Academy of Sciences (i.e., BEIR VII) and UNSCEAR, and the finalization of new ICRP recommendations this year.

Desired Outcome:

NRC participation in NCRP processes is intended to inform and influence the development of NCRP recommendations to ensure that they have a sound scientific basis and are consistent with Commission policies.

Activities:

In 2006, NCRP published NCRP Report No. 153, "Information Needed to Make Radiation Protection Recommendations for Space Missions Beyond Low-Earth Orbit." In addition, and of particular interest to NRC and the radiation protection community, NCRP continues to revise NCRP Report No. 93, "Ionizing Radiation Exposure of the Population of the United States," (1987). Publication is anticipated in late 2008. NCRP held its 42nd annual meeting in April 2006 and selected the topic of "Chernobyl at Twenty" to provide a forum for national and international scientists to engage in a comprehensive retrospective review and analysis of the effects of the Chernobyl nuclear accident on human health and the environment. The 43rd annual meeting addressed the topic of "Advances in Radiation Protection in Medicine" and was held on April 16–17, 2007, in Arlington, Virginia.

Plans for Interaction and Evaluation:

As an NCRP Collaborating Organization, the NRC will have an opportunity to review and comment on draft reports as they become available. As a part of the review, staff will evaluate the impact of these reports on NRC's radiation protection regulations.

Title: International Atomic Energy Agency Environmental Protection Action Plan

Background/Context:

In association with ICRP's new work on environmental protection recommendations, IAEA sponsored an international workshop on protection of the environment in Stockholm, Sweden, in October 2003. The conference concluded that "While accepting that there remain significant gaps in knowledge and that there needs to be continuing research ... there was an adequate knowledge base to proceed and [the conference] strongly supported the development of a framework for environmental radiation protection." It also found that "the time is ripe for launching a number of international initiatives to consolidate the present approach to controlling radioactive discharges to the environment by taking explicit account of the protection of species other than humans."

The Board of Governors approved an action plan to guide IAEA activities in September 2005. The action plan is to be a bottom-up, step-wise approach, and it incorporates key NRC views.

Desired Outcome:

The NRC staff's activities in this area seek to influence the IAEA Action Plan and subsequent actions and activities to ensure that proposed activities have an adequate scientific basis, and promote the Commission view that a separate framework for radiological protection on non-human species is unnecessary.

Activities:

NRC staff participated in the first IAEA coordination meeting in January 2006, successfully promoting the Commission's views.

Plans for Interaction and Evaluation:

The staff will continue to monitor IAEA activities and participate in the annual action plan coordination meeting. Staff will continue to promote the Commission view that a separate framework for radiological protection on non-human species is unnecessary.

Title: International Atomic Energy Agency Basic Safety Standards

Background/Context:

The International Basic Safety Standards (BSS), which are based on the ICRP recommendations, form the basis for the control of radiation and radioactive materials in many countries worldwide. IAEA uses the BSS in its program of information transfer and technical assistance provided to its member states.

IAEA last revised the BSS in a multiyear process following the publication of ICRP recommendations in 1991. IAEA has begun to consider a revision, in part to review the ICRP revised recommendations and in part to update the BSS based on developments over the past 10 years.

Desired Outcome:

NRC participation in an IAEA review of the BSS is intended to inform and influence international safety standards to reflect positions and policies consistent with Commission direction and NRC's regulatory structure.

Activities:

NRC staff has participated in consultant meetings, the IAEA Radiation Safety Standards Committee (RASSC), and the Commission on Safety Standards (CSS) to influence proposals by the IAEA secretariat for a rapid revision of the BSS. The staff did not believe that the fast pace of the proposal was warranted because ICRP has not yet published its recommendations and because no pressing safety issues need to be resolved in the current BSS. The staff was successful in gaining support from other member states to slow the process and use 2006 to review the various technical areas to determine the types of changes to consider. At the RASSC meeting in April 2006, NRC staff again led efforts with a coherent proposal and path forward, including suggestions for additional consultancies to: (1) consider the role of the BSS in the revised IAEA system of safety standards; and (2) develop criteria for determining if a proposed change is sufficiently important to be considered.

Plans for Interaction and Evaluation:

NRC staff, through the IAEA RASSC and CSS and other venues, will remain aware of and be prepared to participate in activities as IAEA continues to develop plans for a review and possible update of the BSS.