

## **Activities Associated with Evaluating Scientific Information about Radiation Health Effects 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) that 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 developed the latest DS in 2002 (AKA, 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. The National Academy of Sciences Biological Effects of Ionizing Radiation (BEIR) VII committee reviewed the preliminary data, and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) will use the final published data.

### **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 (ICRP) have reviewed new cancer incidence data for the atomic bomb survivors that was recently published as RERF Report No. 8-06, "Solid Cancer Incidence in Atomic Bomb Survivors," in the peer-reviewed journal *Radiation Research*.

Enclosure

The staff of the U.S. Nuclear Regulatory Commission (NRC) plans to continue to monitor the research published by RERF, including the review and assessment of cancer and noncancer disease among survivors, through review of published open literature, the RERF Web site, and attendance at various related conferences (e.g., held by the National Council on Radiation Protection and Measurements (NCRP), UNSCEAR, and the National Academies). In particular, the staff will monitor radiation-induced cataract formation and determine if ocular radiation protection standards are adequately protective. In addition, the staff will revise the cancer mortality coefficients, if appropriate, based on the new Japanese data. The staff will review these reports and evaluate their impact on the 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 continues to 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:**

During the past year, the projects supported by the Low Dose Radiation Research Program have continued to expand current understanding of normal tissue responses to low doses of radiation. More than 400 peer-reviewed publications have been issued as a result of Low Dose Radiation Research Program projects, 34 of which were published in 2007. 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 seventh workshop January 21–23, 2008, 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. NRC staff from the Office of Nuclear Regulatory Research (RES) and the former Advisory Committee on Nuclear Waste and Materials 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 U.S. National Academies' Nuclear and Radiation Studies Board (NRSB) 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 purview of NRSB include scientific studies that examine the health effects, consequences, and amelioration of exposure to ionizing and nonionizing 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 NRSB through attendance at meetings and symposiums to keep abreast of the latest studies on the biological effects of radiation exposure. The staff will use the information obtained as part of the technical basis for updating Title 10, Part 20, "Standards for Protection against Radiation," of the *Code of Federal Regulations* (10 CFR Part 20).

**Activities:**

NRSB routinely hosts open sessions for researchers to present their work. For example, topics of staff interest at the winter meeting included medical exposures to radiation and the American College of Radiology's actions to optimize radiation exposure, Congressional Budget Office analysis of the economics of spent fuel processing, and new developments in the Yucca Mountain program.

The staff attended the Sixth Annual Gilbert W. Beebe Symposium on December 12, 2007. The theme of the symposium was "Sixty Years of ABCC/RERF<sup>1</sup>: Past Contributions and Future Directions." The review of major scientific contributions included "Radiation Effects on Cancer Risks in the Life Span Study (LSS) and In-Utero Cohorts"; "The Adult Health Study: Clinical Health Assessments, Biospecimens, and Medical Support for the A-Bomb Survivors"; and "ABCC/RERF Epidemiology: Non-Cancer Diseases in the LSS Population and Cancer and Multifactorial Disease in the F<sub>1</sub> Population."

NRSB provided oversight to the committee that was preparing the Radiation Source Use and Replacement study. This study, required by the Energy Policy Act of 2005, explored alternatives to certain sources of radioactive material. The report was released on February 20, 2008.

**Plans for Interaction and Evaluation:**

The staff will continue to monitor NRSB activities and will attend applicable meetings and symposiums. The spring meeting (May 29, 2008) and summer meeting (September 11, 2008) will take place at the National Academies building in Washington DC. The Seventh Annual Beebe symposium is scheduled for December 3, 2008, in Washington, DC (Kech Center). The theme of the symposium has not been announced.

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<sup>1</sup> ABCC/RERF—Atomic Bomb Casualty Commission/Radiation Effects Research Foundation

**Title: United Nations Scientific Committee on the Effects of Atomic Radiation**

**Background/Context:**

UNSCEAR is chartered 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, agencies of the United Nations, 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, "Sources, Effects and Risks of Ionizing Radiation," as part of the technical basis to justify the last major revision of its radiation protection standards.

**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 staff will use the UNSCEAR report as a primary technical basis for developing and revising radiation risk estimates in 10 CFR Part 20.

**Activities:**

UNSCEAR held its 55th session in Vienna, Austria, May 21–25, 2007. The UNSCEAR Secretariat received significant guidance for consideration during the review of five draft reports that will be reviewed and finalized by UNSCEAR during the 56th session in 2008. Four reports that received very close scrutiny were R663, "Medical Radiation Exposures"; R664, "Exposures of the Public and Workers from Various Sources"; R665, "Exposures from Radiation Accidents"; and R666, "Effects of Ionizing Radiation on Non-Human Biota." UNSCEAR will review these draft reports again in 2008 with the intent of finalizing the reports and approving them for publication in early 2009.

The Secretariat expects that UNSCEAR will publish its 2006 report, "Effects of Ionizing Radiation," in two volumes during the first half of 2008. Volume 1 will comprise the main text of the 2006 report to the General Assembly and two scientific annexes on epidemiological studies of radiation and cancer and epidemiological evaluation of cardiovascular disease and other noncancer diseases following radiation exposure. Volume 2 will comprise the remaining three scientific annexes on nontargeted 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.

**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 by 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-2008. The Committee will hold its 56th session in Vienna on July 10–18, 2008.

**Title: International Commission on Radiological Protection General Radiation Protection Recommendations**

**Background/Context:**

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 on December 18, 2007, as ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection." The revision effort was 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 final ICRP publication recommendations to ensure that they are supported by a scientifically sound technical basis.

**Activities:**

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 published them as ICRP Publication 103 on December 18, 2007, as noted above.

**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. During the first half of 2008, the staff expects that ICRP will make drafts reports available on reference animals and plants, living in contaminated lands, and emergency exposure situations. The staff will review the final ICRP recommendations and evaluate the impact, if any, on the NRC's radiation protection regulations. The staff will provide options on the adoption of ICRP recommendations for Commission consideration in December 2008.

**Title: International Commission on Radiological Protection Environmental Protection Recommendations**

**Background/Context:**

ICRP has established an activity on the 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, "A 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.

ICRP created 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.

**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 nonhuman species is unnecessary.

**Activities:**

ICRP devoted a chapter to the protection of the environment in both the 2006 and 2007 versions of the draft ICRP recommendations. In both instances, the staff informed 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. The NRC staff reiterated this position at two workshops sponsored by the Nuclear Energy Agency (NEA) on the draft ICRP recommendations. ICRP retained the chapter in the final recommendations published in December 2007.

**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. On January 7, 2008, ICRP provided the draft report, "Environmental Protection the Concept and Use of Reference Animals and Plants." The staff reviewed the document and provided comments to ICRP and to the Commission as an information paper in SECY-08-0038. The staff also briefed the former Advisory Committee on Nuclear Waste and Materials on its review of the draft document in February 2008.



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

**Background/Context:**

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 released general radiation protection recommendations in NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," issued 1993. The staff anticipates that NCRP will want to reiterate and update its position on radiation protection issues since the publication of additional data on the biological effects of ionizing radiation by the National Academies (i.e., BEIR VII) and the publication of the new ICRP recommendations.

**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 2007, NCRP published NCRP Report 157, "Radiation Protection in Educational Institutions." The staff reviewed and provided comments on two draft documents, "Risk to the Thyroid from Ionizing Radiation," and "Management of Persons Contaminated with Radionuclides." In addition, and of particular interest to the NRC and the radiation protection community, NCRP continues to revise NCRP Report 93, "Ionizing Radiation Exposure of the Population of the United States," issued 1987. Publication is anticipated in late 2008. NCRP held its 43rd annual meeting in April 2007 in Crystal City, Virginia, on the topic of advances in radiation protection in medicine. The 44th annual meeting, held on April 14-15, 2008, in Rockville, Maryland, addressed the topic of low-dose and dose-rate radiation effects and models.

**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, the staff will evaluate the impact of these reports on the NRC's radiation protection regulations.

**Title: Nuclear Energy Agency Committee on Radiation Protection and Public Health**

**Background/Context:**

The NEA Committee on Radiation Protection and Public Health (CRPPH) is an internationally recognized committee of radiation protection experts that works to assist member countries in the regulation and implementation of the system of radiological protection by identifying and addressing conceptual, scientific, policy, regulatory, operational, and societal issues in a timely and prospective fashion, and by clarifying their implications. CRPPH meets annually to provide a forum for the exchange of information and experience between national radiation protection and public health authorities.

**Desired Outcome:**

The NRC interacts with CRPPH in order to participate in an international forum to identify emerging issues in radiological protection science, assist in the development of radiation protection policies and practices that best reflect state-of-the-art science and technology, seek understanding on questions of common concern regarding the interpretation of international standards, and advance concepts to make the system of radiological protection more simple and transparent.

**Activities:**

The 65th session of CRPPH met May 30–June 1, 2007, to discuss issues associated with the topical areas of emergency management, occupational radiation exposure, the system of radiation protection, and ongoing and emerging radiation protection issues. This session also marked the 50th anniversary of CRPPH. A special 1-day session convened on May 31, 2007, embedded within the 2007 annual meeting, to mark this occasion. Sessions were designed to recognize the achievements of CRPPH, identify potential emerging challenges for the radiological protection community, and identify new opportunities and approaches to address the emerging challenges. Significant topics included discussion of the activities of expert groups addressing ICRP activities to develop new recommendations, occupational exposures at nuclear power plants, emergency preparedness, the role of stakeholders, and future CRPPH work.

**Plans for Interaction and Evaluation:**

The staff will continue to monitor CRPPH activities and review documents as needed. The next CRPPH meeting will take place May 20–22, 2008, at NEA headquarters in Issy-les-Moulineaux (Paris), France.

**Title: Nuclear Energy Agency/International Atomic Energy Agency—Information System on Occupational Exposure**

**Background/Context:**

NEA created the Information System on Occupational Exposure (ISOE) in 1992 to promote and coordinate international cooperation in occupational radiation protection at nuclear power plants. ISOE provides a forum for radiation protection experts from utilities and national regulatory authorities to discuss, promote, and coordinate international cooperative efforts for the radiological protection of workers at nuclear power plants. Since 1993, IAEA has cosponsored the ISOE program, thus allowing the participation of utilities and regulatory authorities from non-Organisation for Economic Co-operation and Development/NEA member countries. The program includes 71 participating utilities in 29 countries, as well as the regulatory authorities of 25 countries. The ISOE databases enable the analysis of occupational exposure data from 401 operating commercial nuclear power plants (representing about 91 percent of the world's total operating commercial reactors) and 80 units undergoing decommissioning.

**Desired Outcome:**

The NRC interacts with the ISOE program to participate in an international forum to exchange occupational exposure data and information for use in dose trend analyses, technique comparisons, and cost-benefit and other analyses facilitating the application of the principle of keeping exposure as low as reasonably achievable in radiological protection programs.

**Activities:**

The 17th annual ISOE Steering Group meeting took place November 14–16, 2007, at NEA headquarters in Issy-les-Moulineaux (Paris), France. Mr. W. Mizumachi (ISOE Chair, Japan) chaired the meeting and noted that, in the context of global changes in the energy market, the role of ISOE in reducing occupational radiation exposure and communicating good radiation protection practices will become increasingly important. The NRC accepted the 2008–2011 terms and conditions for continued ISOE participation on March 3, 2008.

**Plans for Interaction and Evaluation:**

The staff will continue to monitor and participate in ISOE activities and review documents as needed. The next ISOE meeting will take place June 25–27, 2008, in Turku, Finland.

**Title: International Atomic Energy Agency Environmental Protection Action Plan**

**Background/Context:**

In association with new ICRP 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.” The conference 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 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 nonhuman species is unnecessary.

**Activities:**

The staff continued to interact with IAEA during 2007, successfully promoting the Commission’s views. The next coordinating meeting will be held on June 20, 2008 in Bergen, Norway.

**Plans for Interaction and Evaluation:**

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

**Title: International Atomic Energy Agency Basic Safety Standards**

**Background/Context:**

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

**Desired Outcome:**

The NRC's 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 the NRC's regulatory structure.

**Activities:**

The 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. IAEA convened a technical committee meeting in Vienna, Austria, July 16–20, 2007. About 120 participants from 61 countries, international organizations, and professional societies, as well as numerous members of the IAEA Secretariat staff and management, attended the meeting. Additional consultant and joint Secretariat drafting meetings took place in September and November 2007.

**Plans for Interaction and Evaluation:**

The staff will actively participate in drafting meetings and the IAEA RASSC and CSS meetings. It will remain aware of activities as IAEA continues to review and update the BSS. IAEA hosted additional drafting meetings in March and April, 2008, and plans to have a draft for extended review during the RASSC meeting on November 10-14, 2008.