POLICY ISSUE
INFORMATION

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FOR: The Commissioners

FROM: Luis A. Reyes
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SUBJECT: ANNUAL REPORT ON ACTIVITIES ASSOCIATED WITH EVALUATING SCIENTIFIC INFORMATION AND RADIATION PROTECTION RECOMMENDATIONS

PURPOSE:

To update the Commission with regard to the staff's activities to evaluate scientific information about radiation health effects and the radiation protection recommendations of national and international organizations.

BACKGROUND:

In the past, the U.S. Nuclear Regulatory Commission (NRC) has followed the basic radiation protection recommendations of the International Commission on Radiological Protection (ICRP) and its U.S. counterpart, the National Council on Radiation Protection and Measurements (NCRP), in formulating its basic radiation protection standards. The agency's "Standards for Protection Against Radiation," are set forth in Title 10, Part 20, of the *Code of Federal Regulations*. The last major revision of these standards was completed with the publication of a *Federal Register* notice (56 FR 23360) on May 21, 1991.

In response to a staff proposal to update the agency's regulations concerning byproduct and source material (SECY-02-0196), dated November 17, 2003, the Commission provided the following staff direction:

> "… provide the Commission with a comprehensive plan for evaluating the latest scientific information and the recommendations of the international/national radiation protection organizations for possible incorporation into our regulatory activities, policies, and regulations. This plan should include evaluation of all major efforts scheduled to be completed in the next several years, and lead to staff recommendations on the need to revise NRC's regulatory program…"

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The staff subsequently transmitted a review plan to the Commission in SECY-04-0055, and the Commission approved that plan on May 13, 2004. One aspect of that plan involved a staff commitment to provide the Commission with annual status reports, including progress summaries concerning the activities associated with evaluating scientific information about radiation health effects and the radiation protection recommendations of national and international organizations. This paper is the first of those annual status reports. As such, this paper reflects related staff activities that are coordinated by the NRC's Radiation Protection Steering Group, which includes representatives from the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards (NMSS), Nuclear Regulatory Research (RES), Nuclear Security and Incident Response, and State and Tribal Programs (STP).

DISCUSSION:

Ongoing scientific work continues to increase our understanding of the health effects and risks associated with radiation exposure. To date, most of the related understanding has derived from studies of the Japanese atomic bomb survivors. Toward that end, the Radiation Effects Research Foundation (a private, nonprofit organization supported by the governments of Japan and the United States) recently revised the system by which radiation doses are assigned to the atomic bomb survivors from Hiroshima and Nagasaki, and is expected to update its related cancer risk estimates in the near future. Currently, these cancer risk estimates provide the fundamental basis for estimating radiation-induced health effects.

To address the issue of how low doses of radiation affect living organisms, the U.S. Department of Energy initiated a 10-year research program in 1999 to better characterize radiation effects on cells and molecules. Investigators funded under that program meet periodically to discuss progress on individual research projects, and NRC staff representatives participate in these discussions.

Other organizations also review current research findings and develop risk estimates on the basis of their reviews. In the United States, for example, the National Academies published "Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V" in 1990. An update, to be published as BEIR VII (Biological Effects of Ionizing Radiation report No. VII), is currently undergoing review by the National Academies, and may be published by the National Academy Press as early as June 2005. Within 90 days after receiving the BEIR VII report, the NRC staff will assess its possible implications on the agency's regulations and the related Federal Guidance, and will update the Commission regarding the staff's findings, conclusions, and recommendations.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) also periodically examines the effects of radiation exposure from natural and manmade sources and published its most recent major report in 2000. UNSCEAR is currently reexamining the health effects of radiation exposure by evaluating epidemiological studies of radiation and health (cancer and non-cancer illnesses), examining the mechanisms and consequences of radiation exposure in tissues, and examining the dynamics of radionuclides in the environment and their impact on ecosystems. UNSCEAR may publish its next report in 2007.

The ICRP periodically reexamines its recommendations using scientific information, such as UNSCEAR reports, to decide whether new recommendations are needed. As part of that effort, the ICRP is currently consolidating, simplifying, and updating its recommendations. To evaluate and participate in that revision, NRC staff representatives have provided comments directly to the ICRP and through other organizations such as the Nuclear Energy Agency. In addition, the staff has facilitated meetings between members of the ICRP Main Commission and NRC staff and stakeholders. The staff will also review the supporting documentation for the ICRP's revised recommendations, which was made available for review and comment during April 2005. The staff will forward its comments to the ICRP in time for incorporation before the ICRP releases the next draft of its recommendations for review and comment in spring 2006.

The NCRP may also update its radiation protection recommendations following the publication of the BEIR VII and UNSCEAR documents and the finalization of any new or revised ICRP recommendations.

The attachment to this paper summarizes each of the staff's related ongoing activities. The NRC staff have budgeted resources to evaluate scientific information about radiation health effects and the radiation protection recommendations of national and international organizations for the next two fiscal years. STP will solicit comments on these documents from the Agreement States, the Organization of Agreement States, and the Conference of Radiation Control Program Directors. These budgeted resources will enable the staff to review the ICRP's supporting documentation and the National Academies' BEIR VII report this summer, followed by the next draft of the ICRP's recommendations next spring. Based on its review of these documents, the staff will assess the possible implications on the NRC's regulations and the related Federal guidance, and will update the Commission regarding its findings, conclusions, and recommendations. Consequently, the staff believes that the NRC should not undertake any significant revision of its radiation protection regulations until after the staff reviews both the BEIR VII report and the final ICRP recommendations and their supporting documentation.

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Attachment: Activity Summaries

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 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, which will be reviewed by the National Academy of Sciences and 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, etc.) 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 being 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 NRC staff will review the RERF assessment of how the revised dosimetry affects the radiation risk estimates for solid cancer and leukemia among the atomic bomb survivors. The staff will also continue to monitor the review and assessment of non-cancer disease among survivors, through both the RERF activities and those sponsored by UNSCEAR.

Attachment

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 based on a strong scientific foundation. In response, DOE's 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 our 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 mrem (1 mSv), 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: how radiation damages DNA and how the cell responds by repairing this damage; how radiation-induced DNA damage differs from day-to-day damage induced by cellular metabolism; how cells respond or adapt when repeatedly exposed to radiation; how irradiation of a single cell impacts those cells surrounding it (bystander effects); and 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 available at http://www.er.doe.gov/production/ober/lowdose.html 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. The fifth workshop was held on April 25–27, 2005, at the Hyatt Regency in Bethesda, Maryland. NRC staff representatives participated in that workshop to assess the impact (if any) that the DOE research program may have on the NRC's regulatory activities in the near future.

Title: Biological Effects of Ionizing Radiation

Background/Context:

In 1996, the NRC staff recommended sponsoring a study under which the National Academy of Sciences would conduct a comprehensive review of the health risks associated with exposure to ionizing radiation. In so doing, the staff intended that review to be a thorough, objective, scientific examination of recent health effects studies that have concluded since the National Academies published "Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V" in 1990. The Commission approved that recommendation in COMSECY-96-005, dated April 2, 1996. The resultant Biological Effects of Ionizing Radiation (BEIR) report is currently undergoing review by the National Academy of Sciences, and may be published by the National Academy Press as early as June 2005. Within 90 days after receiving that report, the NRC staff will provide recommendations to the Commission regarding the implications of BEIR VII for NRC regulations, Federal Guidance, and risk harmonization.

Desired Outcome:

The National Academy of Sciences should provide an accurate 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, evidence of thresholds (or lack thereof) in dose response relationships, and factors that might influence risk assessment. The staff also hopes that this review will describe the most appropriate risk models for all cancer sites and other outcomes for which adequate data exist to support a quantitative estimate of risk, including non-cancer disease. The staff could then use that information to update the risk estimates used in assessing health risks from radiation exposures.

Activities:

The NRC initiated the BEIR VII project in October 1998 as a 36-month program review. The BEIR VII sponsors subsequently requested that the study be extended to allow for the development and analysis of new information concerning radiation exposure of Japanese atomic bomb survivors. Additional requests by the National Academy of Sciences have further extended the BEIR VII study to June 2005 to allow RERF investigators to complete the development of an updated dosimetry system (as previously described) and revised risk assessments for cancer incidence. The National Academy of Sciences has since completed the draft BEIR VII report, which was put into their internal peer review process in early February 2005.

Plans for Interaction and Evaluation:

The NRC staff will review the BEIR VII report when it becomes available (as early as June 2005), and will then prepare a written review for the Commission, including an assessment of the report's possible implications for NRC regulations, Federal Guidance, and risk harmonization.

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

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, exclusively use UNSCEAR reports as the technical basis for their recommendations and decisions. UNSCEAR's work is also of significant interest to many U.S. agencies, including the NRC. For example, the staff used several annexes contained in the UNSCEAR 1998 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 its next report in 2006 or 2007.

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. A thorough review and analysis of the health effects attributed to exposure to radioactive materials released into the environment during the 1986 Chernobyl accident is needed. The UNSCEAR report is a primary technical basis for developing and revising radiation risk estimates.

Activities:

The UNSCEAR held its 52nd session in Vienna, Austria, on April 26–30, 2004, to consider new information relevant to assessing sources of radiation, the exposure to which these sources give rise, and the resultant effects. The Committee is currently reviewing information for inclusion in the next UNSCEAR report, which may be published in 2006 or 2007. That report is expected to reexamine the health effects of radiation exposure by evaluating epidemiological studies of radiation and health (cancer and non-cancer illnesses), examining the mechanisms and consequences of radiation exposure in tissues, and examining the dynamics of radionuclides in the environment and their impact on ecosystems. The Committee will hold its 53rd session in Vienna, Austria, on September 26—30, 2005.

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 staff will also assess the impact (if any) that a final UNSCEAR report will have on the technical basis supporting the NRC's rulemaking activities.

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. The 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.

The ICRP made a draft set of recommendations available for public review and comment on its Web site (www.icrp.org) in June 2004, and has since received numerous comments. The ICRP is also continuing to develop the supporting documents that describe the technical bases for the draft recommendations, which were made available for public review in April 2005. It is likely that the ICRP will offer a second opportunity to review the draft ICRP recommendations in spring 2006.

Desired Outcome:

NRC participation is intended to influence the drafting and revision of ICRP recommendations to ensure that they are supported by scientifically sound technical bases. It is important that the recommendations continue to provide a sound basis for U.S. regulations and are implementable.

Activities:

The NRC staff developed comments on the draft ICRP recommendations for Commission endorsement, and submitted the Commission-approved comments to the ICRP in January 2005. Those comments were consistent with many that the ICRP received from others. The staff also hosted an Interagency Steering Committee on Radiation Standards (ISCORS) workshop on the draft recommendations in September 2004, which provided a opportunity for the ICRP's Chairman and Vice Chairman to interact directly with Federal agency representatives and members of the public concerning the draft recommendations.

Plans for Interaction and Evaluation:

The staff will continue to monitor the ICRP's activities, review documents as they become available, and provide technical advice directly to the various ICRP committees. The staff will also prepare comments for Commission endorsement when the supporting documents become available for public review, and during the anticipated second round of public review of the revised recommendations in spring 2006.

Title: ICRP Environmental Protection Recommendations

Background/Context:

The ICRP has established a new task group on protection of the environment to develop a radiation protection policy and establish an environmental protection framework based on ethical and philosophical principles. The outline for the framework was published as ICRP Publication 91, "A Framework for Assessing the Impact of Ionizing Radiation on Non-Human Species" (2003). The new framework, which will likely be included in the ICRP's next set of recommendations, is intended to be a parallel approach to 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 as a basis for more fundamental understanding and interpretation of the relationships between exposure and dose for a few clearly defined types of animals and plants.

The ICRP recently announced the creation of Committee 5 for the protection of non-human organisms. This committee was formed to specifically pursue work in the environmental protection area.

Desired Outcome:

NRC participation in the ICRP process is intended to inform and influence the development of ICRP recommendations to ensure that they have a sound scientific basis and are consistent with U.S. policies.

Activities:

There have been no activities in this topical area. The ICRP has not provided any documents for review or comment. NRC staff included comments on environmental protection in its January 2005 response concerning the draft 2005 ICRP recommendations.

Plans for Interaction and Evaluation:

The staff will review draft ICRP materials when they become available, and will then prepare comments and coordinate with the Commission. Although the ICRP has not yet released a schedule for public consultation, the staff understands that the ICRP task group may release a draft report this summer.

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's 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. The NCRP last issued general radiation protection recommendations when it published NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," in 1993. The NRC staff anticipates that the 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 in 2006 or 2007.

Desired Outcome:

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

Activities:

The NCRP published three reports in 2004, including Report No. 146, "Approaches to Risk Management in Remediation of Radioactively Contaminated Sites" and NCRP Statement No. 10, "Recent Applications of the NCRP Public Dose Limit Recommendation for Ionizing Radiation." The NCRP will begin revising Report No. 93, "Ionizing Radiation Exposure of the Population of the United States" this year, and should publish the revised report in 2008. The NCRP held its 41st annual meeting in March 2005, and selected the topic of "Managing the Disposition of Low-Activity Radioactive Materials" to foster discussion of related issues and concerns and provide a forum for exploring risk-informed decision-making processes.

Plans for Interaction and Evaluation:

As an NCRP Collaborating Organization, the NRC will have an opportunity to review and comment on draft reports. The staff will review and prepare comments on draft NCRP materials as they become available.

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 control of radiation and radioactive materials in many countries worldwide. As such, the International Atomic Energy Agency (IAEA) uses the BSS in its program of information transfer and technical assistance to its Member States.

The IAEA last revised the BSS in a multi-year process following the publication of revised ICRP recommendations in 1991. The IAEA is expected to assess whether changes are needed following the publication of the revised ICRP recommendations in 2005.

Desired Outcome:

NRC participation in an IAEA review of the BSS is intended to inform and influence the development of international safety standards to ensure that the positions and policies are consistent with U.S. activities and Commission direction.

Activities:

NRC staff representatives participated in a consultants' meeting on possible revision of the BSS on January 31 – February 5, 2005 (see ADAMS Accession #ML050600331). The consultants recommended a two-phased approach to revising the BSS. The first phase would involve an expanded amendment of the BSS, making changes to ensure consistency with the subsequent publications. This would lend stability to the process, making changes only where needed and streamlining the existing BSS. Participants recommended that the BSS should be comprehensive and continue to address both practices and interventions. The second phase would involve a major revision of the BSS, possibly in 6 to 8 years, which could take into account any new ICRP recommendations.

Plans for Interaction and Evaluation:

Through the IAEA Commission on Safety Standards and Radiation Safety Standards Advisory Committee and other venues, the NRC staff will remain aware of, and be prepared to participate in activities once the IAEA finalizes its plans for a review and possible update of the BSS.

Title: IAEA Environmental Protection Action Plan

Background/Context:

The IAEA sponsored a workshop on protection of the environment in Stockholm, Sweden, in October 2003. That workshop 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 workshop] strongly supported the development of a framework for environmental radiation protection." The workshop 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 IAEA is currently developing an action plan based on the workshop recommendations.

Desired Outcome:

NRC participation is intended to influence the development of the IAEA action plan, and subsequent action, to ensure that proposed activities have an adequate scientific basis that is consistent with Commission direction.

Activities:

NRC staff representatives participated in an IAEA technical committee meeting on the IAEA action plan in June 2004 (see ADAMS Accession #ML041760535). The action plan is to be a bottom-up, stepwise approach, and key Commission views were successfully incorporated into the plan. The IAEA will formally transmit the draft action plan to Member States for review before seeking approval from the IAEA Board of Governors.

Plans for Interaction and Evaluation:

The NRC staff will review and prepare comments for Commission endorsement after the IAEA sends the action plan to Member States for review.

Title: Nuclear Energy Agency

Background/Context:

Through expert groups under the Committee on Radiation Protection and Public Health, the Nuclear Energy Agency (NEA) is providing its views on how the ICRP system of radiation protection should evolve, as well as its views on the development of guidance concerning radiological protection of the environment. The NEA expert groups are studying early concepts that the ICRP considered, and continuing to assess the potential regulatory and guidance implications that would result if the ICRP should finalize its draft 2005 recommendations. The NEA's Radioactive Waste Management Committee has also provided comments concerning the suitability of the radiation protection framework for waste disposal activities.

Desired Outcome:

NEA activities should help to ensure that the final ICRP recommendations will best serve the needs of national and international radiation protection policy makers, regulators, and implementers.

Activities:

NRC staff representatives participated in an expert group meeting in November 2004 to assist in preparing the NEA's comments on the ICRP's draft 2005 recommendations (see ADAMS Accession #ML043440186). In so doing, the NRC participants were able to incorporate all of the Commission's key comments and messages into the NEA comments. A good degree of consistency was also achieved between the NRC's positions and those of other international regulatory organizations.

Plans for Interaction and Evaluation:

NRC staff representatives will participate in future expert group meetings as they are scheduled. Tentative plans call for a meeting in June 2005, when several ICRP supporting documents are expected to become available for public review and comment.