

Plan for Evaluating Scientific Information and Radiation Protection Recommendations

Introduction

The staff will participate in, and evaluate the results of, national and international radiation protection organizations' activities to ensure that NRC regulations and guidance have a sound basis in science, represent the current understanding of radiation health effects, and provide a risk-informed and performance-based graded approach to radiation protection. This plan addresses research activities to support scientific basis development, and participation in the development of international and national recommendations, regulations, and guidance. It is supported by the "Radiation Protection and Health Effects Research Program Plan" contained in SECY-04-0030, and provides details for many of the activities identified in the research plan.

Purpose

To guide the staff in evaluating current national and international radiation protection activities and to support continued evolution of NRC's regulatory framework as a coherent risk-informed system based on sound up-to-date scientific information.

Background

The NRC has generally 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 Standards for Protection Against Radiation, 10 CFR Part 20, were last revised in 1991 with respect to the overall approach to radiation protection (56 FR 23360, May 21, 1991), and are based in part on the ICRP recommendations published in ICRP Publication 26 (1977) and ICRP Publication 30 (1978). However, NRC did adopt limits for protection of the public of 100 mrem (1 mSv) per year based on indications that the ICRP would recommend this value in ICRP 60.

In Publication 60 (1991), the ICRP also recommended a reduction in the occupational dose limit from an equivalent of 5 rem (50 mSv) per year to an average of 2 rem (20 mSv) per year with some allowance for year-to-year flexibility. Since the release of Publication 60, ICRP has published additional recommendations for specific situations and published more sophisticated biophysical models for internal dosimetry. ICRP is currently engaged in efforts to consider, simplify, and update its recommendations which it intends to publish in 2005. In parallel, ICRP has initiated development of a framework for protection of the environment to fill a conceptual gap in the overall approach to radiation protection. In addition, the ICRP environmental framework will provide a basis for assessing impacts in situations in which humans may not be present.

Scientific examination of the effects of radiation has also continued in a variety of venues. Under the Radiation Effects Research Foundation (RERF), a new dosimetry system for the Hiroshima and Nagasaki atomic bomb survivors has been developed, and new risk estimates are expected in the near future. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) periodically examines radiation risks, with the last major report

published in 2000. A report on hereditary effects was published in 2001. In the United States, the National Academy of Sciences' Committee on Biological Effects of Ionizing Radiation (BEIR) published "Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V" in 1990. An update, to be published as BEIR VII, is currently underway and is expected to be published in 2005. The information developed in these reports on radiation health risks has been used in the past in setting radiation protection standards. Also, the Department of Energy (DOE) is sponsoring a 10-year radiation research program to establish a better technical basis for future radiation protection standards and guidelines.

Discussion

This plan is organized by categories of activities:

- A. Scientific Basis Development
- B. International and National Recommendations Development
- C. National and International Regulations and Guidance

Within each category, the plan provides a brief background and context for each activity, as well as the corresponding plans for interaction and evaluation of that activity. Specific milestones and deliverables will be developed once the information is available. Most of these activities are identified in the "Radiation Protection and Health Effects Research Program Plan" (see SECY-04-0030). The research program plan and this evaluation and recommendation plan are considered to be living documents and will be updated as necessary to reflect the current status of activities.

A. Scientific Basis Development

Activities in this category are aimed at continuing to refine and understand the health effects of exposure to ionizing radiation.

1. Radiation Effects Research Foundation (RERF)

Background/Context

The RERF research program focuses on epidemiological studies of mortality and cancer incidence among atomic bomb survivors from Hiroshima and Nagasaki, Japan. A major reassessment of the systems used to determine radiation doses (DS02) was requested by the DOE and the Japanese Ministry of Health, Labour and Welfare in an effort to resolve an apparent discrepancy between neutron activation calculated by the existing DS86 dosimetry system and as measured in material (e.g., copper metal) exposed to neutrons at the time of the bombing. This new dosimetry system, DS02, will be used to reevaluate the risk assessments for cancer incidence and mortality among the atomic bomb survivors. This information will be published in a peer-reviewed journal and shared with the National Research Council/National Academies committee evaluating the biological effects of ionizing radiation. This effort is critical because knowledge of the radiation risk factors comes almost entirely from data on the Japanese atomic bomb survivors.

Desired Outcome

Although significant changes in risk estimates are not expected from the creation of DS02 and a revision of the cancer incidence and mortality risk estimates among the

atomic bomb survivors, the improved dosimetry calculations and refined shielding considerations should reduce uncertainty and provide increased confidence in the validity of risk assessments.

Plans for Interaction and Evaluation

The RERF staff plans to publish the revised assessment of cancer incidence and mortality in a peer-reviewed journal by 2005.

The NRC staff will review and prepare comments on this assessment. This review will be incorporated into a broader NRC technical basis review (estimated completion mid-2005).

Resources

Estimated staff resources - 0.05 FTE in FY05. ⁽¹⁾

2. United Nations Scientific Committee on the Effects of Atomic Radiation

Background/Context

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), a scientific committee of the General Assembly, is the body in the United Nations system with a mandate to assess and report levels of exposure to ionizing radiation and the effects on humans and the environment. Governments and organizations rely on the committee's 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) exclusively use UNSCEAR reports as their technical basis for recommendations and decisions. UNSCEAR's work also is of significant interest to many U.S. agencies, including the NRC. For example, several annexes in the UNSCEAR 1988 Report were used as part of the technical basis justifying the 1990 revision of 10 CFR Part 20. The Scientific Committee meets annually and issues a comprehensive report every 2 to 5 years. The Scientific Committee currently is considering the inclusion of eight scientific annexes and two overview annexes in the next UNSCEAR report, which should be published in 2006.

Desired Outcome

UNSCEAR will address the effects of exposure to radiation, evaluate epidemiological studies of radiation and health (cancer and noncancer illnesses), examine the mechanisms and consequences of radiation exposure in tissues, and examine the dynamics of radionuclides in the environment and their impact on ecosystems in its next report. The later annex will be used by ICRP Committee 5 during its review and preparation of recommendations for environmental protection.

Plans for Interaction and Evaluation

The staff will continue to support the U.S. delegation to UNSCEAR by reviewing draft annexes as they become available and providing technical guidance to the U.S. delegation and the UNSCEAR secretariate during committee deliberations. The staff will assess and report on what impact, if any, a final UNSCEAR report will have on the technical basis supporting NRC rulemaking activities.

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

Resources

Estimated staff resources - 0. 10 FTE each in FY 04 and FY05 and 0.25 in FY06. ⁽¹⁾

3. Biological Effects of Ionizing Radiation Committee

Background/Context

Both Federal and State technical staff rely, in part, on Biological Effects of Ionizing Radiation (BEIR) studies of the National Academies to provide a scientific benchmark to inform the development of regulatory standards and recommendations. New information has prompted renewed questioning of the postulated linear nonthreshold dose-response relationship at low levels of exposure (e.g., natural background or very small fractions of natural background). Such speculation has raised questions as to how, in view of current biologic and epidemiologic information, regulatory bodies should characterize risks associated with the doses and dose rates experienced by radiation workers and members of the general public at small fractions of background. In 1996, the National Academies, at the request of NRC, the Environmental Protection Agency (EPA), DOE, and Department of Defense initiated a new study (BEIR VII) to review and update assessments of risks related to low-dose, low-LET and neutron radiation and explore what is known regarding the biologic processes determining those risks. This study will incorporate the most current information from the RERF, including updated risk estimates using the new DS02 dosimetry system when it becomes available.

Desired Outcome

The National Academies will provide an assessment of the current status and relevance to risk models of biologic data and models of carcinogenesis, including a critical assessment of all data that might affect the shape of the response curve at low doses, evidence of thresholds (or the lack thereof) in dose-response relationships, and the influence of adaptive responses and radiation hormesis. The National Academies also will provide appropriate risk models for all cancer sites and other outcomes for which there is adequate data to support a quantitative estimate of risk, including benign disease and genetic effects. The information will be used to update risk estimates used in assessing radiation doses.

Plans for Interaction and Evaluation

The staff will review, prepare comments on, and keep the Commission informed on materials when they become available. It is unlikely the RERF data will be available for consideration by the BEIR VII committee before October 2004. Although National Academies staff forecast a late-2004 publication date, the NRC staff predicts that a BEIR VII report will not be publicly available before mid-2005.

Resources

Estimated staff resources - 0.05 FTE in FY04 and 0.25 FTE in FY05 and FY06. ⁽¹⁾

4. DOE Low-Dose Radiation Research Program

Background/Context

In 1999, the DOE initiated a research program, at the request of Congress, to establish risk assessment standards and guidelines that are based on a strong scientific and

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

mechanistic basis rather than on the extrapolation of responses seen at high doses. Research areas funded by DOE range from single cell studies to those on more complex tissues and organ systems. Efforts are being made to study the shape of the radiation dose response relationship and to evaluate the usefulness of the mechanistic studies on risk assessment. The research program currently is projected to last 10 years at a funding level of about \$20 million a year. Scientific findings are being published in peer-reviewed journals and discussed at public workshops sponsored by DOE. These technical publications also are being reviewed by the BEIR VII committee for inclusion into the committee's report.

Desired Outcome

New techniques and instrumentation are being developed that can be used to measure biological and genetic changes following low doses (< 10 mGy or 1 rad) of radiation. This data will help to better characterize radiation effects on cells and molecules and provide additional technical basis for developing regulatory standards and guidance.

Plans for Interaction and Evaluation

The staff will continue to participate in DOE-sponsored workshops to review and discuss scientific results from individual projects. The staff will critique published materials as they are made available and provide technical feedback to the DOE project managers. The staff will ensure that any available DOE results are considered by both the BEIR committee and UNSCEAR for inclusion in their reports.

Resources

Estimated staff resources - 0.05 annually for length of program. ⁽¹⁾

B. International and National Recommendations Development

1. ICRP General Radiation Protection Recommendations

Background/Context

For several years ICRP has been discussing the need to revise its current recommendations for protection from radiation to reduce the complexity that has evolved over time. The aim of the revision is to update the system of radiation protection, and make it more coherent and less confusing. The general recommendations for protection for humans were last published as ICRP Publication 60 in 1991.

The NRC staff has participated in the revision process by providing comments on early draft documents to the ICRP. Also, staff members are providing technical advice to ICRP committees and participate as members of Nuclear Energy Agency (NEA) Expert Groups which are providing comments on early ICRP drafts. Issues previously identified included the need (or perceived lack thereof) for changes and the lack of a sound scientific basis for proposing numerical changes to the existing recommendations.

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

Desired Outcome

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

Plans for Interaction and Evaluation

ICRP general recommendations are scheduled to be available for public consultation in May 2004. At the suggestion of the ICRP Secretariat, NRC staff plans to host a workshop at NRC headquarters in July 2004. The workshop will provide an opportunity for U.S. stakeholders to discuss the proposed general recommendations with ICRP members. NRC staff will continue to participate in ICRP and NEA committees and expert groups; review drafts and provide technical comments; and keep the Commission informed on draft ICRP recommendations as information becomes available.

Resources

Estimated staff resources - 0.1 FTE annually for the length of the program. ⁽¹⁾

2. ICRP Environmental Protection Recommendations

Background/Context

A new task group on protection of the environment was formed by ICRP to develop a radiation protection policy and establish an environmental protection framework based on ethical-philosophical principles. The framework will likely feed into the ICRP's next set of recommendations. The outline for the framework was published as ICRP Publication 91 in 2003. The new framework is intended to be a parallel approach to protection of humans. The proposed system is designed to be used as a practical tool to help regulators with existing and future regulatory standards. An agreed 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 recently announced the creation of Committee 5 for the protection of nonhuman organisms. This committee was formed to specifically pursue a course of work in the environmental protection area.

Desired Outcome

NRC participation in an ICRP process is intended to inform and influence the development of ICRP recommendations to ensure that there is a sound scientific basis for them and that it is consistent with U.S. policies.

Plans for Interaction and Evaluation

The staff will review, prepare comments on, and keep the Commission informed on draft ICRP materials when they become available. No schedule for public consultation

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

has been released. The staff will also review and keep the Commission informed on draft materials developed by ICRP Committee 5.

Resources

Estimated staff resources - 0.1 FTE each in FY04 and FY05. ⁽¹⁾

3. NCRP General Radiation Protection Recommendations

Background/Context

The 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 pertaining to radiation protection. The NCRP last issued general radiation protection recommendations in NCRP Report 116, Limitation of Exposure to Ionizing Radiation (1993). NRC staff anticipate that the NCRP will desire 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 Academies (BEIR VII) and UNSCEAR and the review of the 2005 recommendations of the ICRP.

Desired Outcome

NRC participation in an NCRP process is intended to inform and influence the development of NCRP recommendations to ensure that there is a sound scientific basis for them and that it is consistent with U.S. policies.

Plans for Interaction and Evaluation

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

Resources

Estimated staff resources - 0.05 annually for the length of the program.

C. National and International Regulations and Guidance

1. IAEA Basic Safety Standards

Background/Context

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

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

The BSS was last revised in a multi-year process following the publication of ICRP recommendations in 1991. It is expected that an examination of whether changes are needed will be initiated after publication of the revised ICRP recommendations in 2005.

IAEA recently prepared an action plan designed to implement a strategy for enhancing the agency's safety standards to achieve recognition by all governments and regulatory bodies and provided it to the member states for review. While this plan encompasses more areas than radiation protection issues, the staff will participate in reviewing the development of this action plan.

Desired Outcome

NRC participation in an IAEA review of the BSS and the new action plan to strengthen the role of the IAEA safety standards is intended to influence any revisions to the international safety standards and ensure the policies and positions are consistent with Commission direction.

Plans for Interaction and Evaluation

NRC staff, through the IAEA Commission on Safety Standards, and the Radiation Safety Standards Advisory Committee, and other venues, will remain aware of, and be prepared to participate in, activities once the ICRP recommendations have been published and IAEA has made plans to review and possibly update the BSS.

Resources

Estimated staff resources - 0.05 FTE (date will depend on when IAEA initiates activities).

2. IAEA Environmental Protection Action Plan

Background/Context

The IAEA sponsored an international workshop on protection of the environment, in Stockholm, Sweden (October 2003). The workshop concluded that "while ... there remain significant gaps in knowledge and ... 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." Another conclusion was 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."

In February 2004, the staff participated in a consultants meeting to develop an "IAEA Action Plan on the Protection of the Environment from the Effects of Ionizing Radiation." The Action Plan reflects the guidance from the Commission in response to a strategy laid out in COMSECY-04-0005, 'Staff Participation in an International Atomic Energy Agency Meeting to Prepare a "Draft Action Plan on the Protection of the Environment from the Effects of Ionizing Radiation".'

Desired Outcome

To influence the IAEA Action Plan, and subsequent actions, to ensure that proposed activities have an adequate scientific basis consistent with Commission direction.

Plans for Interaction and Evaluation

The staff will actively participate in a June 2004 IAEA Technical Committee meeting to influence the further development of the Action Plan. The staff is coordinating with DOE and EPA to present a consolidated U.S. position.

Resources

Estimated staff resources - 0.05 FTE each in FY04 and FY05.

3. Nuclear Energy Agency

Background/Context

The Nuclear Energy Agency (NEA), through expert groups under the Committee on Radiation Protection and Public Health, has been providing its views on how the ICRP system of radiological protection should evolve as well as providing views on the development of guidance concerning radiological protection of the environment. Expert groups within NEA have been studying early concepts that were considered by ICRP and are continuing to assess the potential regulatory and guidance implications of publishing draft ICRP recommendations for a system of radiological protection. The NEA Radioactive Waste Management Committee also has provided comments on the suitability of the radiation protection framework for waste disposal activities.

Desired Outcome

NEA activities should help assure that final ICRP recommendations will best serve the needs of national and international radiation protection policymakers, regulators, and implementers.

Plans for Interaction and Evaluation

The staff will continue to participate in the Committee on Radiation Protection and Public Health, and will continue to provide technical review of NEA documents.

Resources

Estimated staff resources - 0.05 FTE annually for the length of the program. ⁽¹⁾

⁽¹⁾ Identified in the Radiation Protection and Health Effects Research Plan (SECY-04-0030)

4. Radiation Protection Guidance for Federal Agencies (General Guidance for Protection of the Public)

Background/Context

Federal guidance is a set of guidelines coordinated with all Federal agencies, and then approved by the President for use by Federal and State agencies responsible for protecting the public from the harmful effects of radiation. This guidance, developed by the EPA using an interagency working group approach, is used by Federal and State agencies responsible for protecting the public from the harmful effects of radiation. The guidance presents recommendations for individuals exposed to environmental sources of radiation. EPA initiated work to develop new Federal Guidance for members of the public more than 10 years ago and published for public comment in 1994. A new draft was reviewed by the Office of Management and Budget and Federal agencies in 2003 which did not include any numeric values, and as a result, EPA was requested to prepare a draft which includes both numeric and nonnumeric options. That draft is now complete and under review within EPA.

Desired Outcome

Staff participation is aimed at achieving new Federal Guidance which reflects current radiation protection philosophies and is consistent with current NRC activities and regulations.

Plans for Interaction and Evaluation

Interagency collaboration will continue to take place through the ISCORS Federal Guidance Subcommittee. The staff will continue to actively participate in this subcommittee and keep the Commission informed on materials as they become available. Draft guidance for members of the public containing both options should be available from EPA in 2004.

Resources

Estimated staff resources - 0.05 FTE each in FY04 and FY05, if needed.

5. Radiation Protection Guidance to Federal Agencies for Occupational Exposure

Background/Context

This guidance, developed by the EPA using an interagency working group approach, is used by Federal and State agencies responsible for protecting the workers from the harmful effects of radiation. This guidance provides general principles, and specifies the numerical primary guides for limiting worker exposure. It applies to all workers who are exposed to radiation in the course of their work, either as employees of institutions and companies subject to Federal regulation or as Federal employees. The Federal Guidance for Occupational Exposure was last updated in 1987, and predated the 1991 ICRP recommendations (ICRP Publication 60).

Desired Outcome

The review and updating of Federal Guidance for Occupational Exposure is coordinated among the Federal agencies to ensure that the need for any revision is appropriately evaluated.

Plans for Interaction and Evaluation

Interagency collaboration will continue to take place through the ISCORS Federal Guidance Subcommittee. The staff will continue to actively participate in this subcommittee and keep the Commission informed on draft documents as they become available.

Resources

Estimated staff resources - 0.05 FTE each in FY04 and FY05, if needed.

6. OSHA Occupational Radiation Protection Regulations

Background/Context

The Occupational Safety and Health Administration (OSHA) sets standards for overall safety of the work place, including physical, chemical, sound and light hazards, and nonionizing radiation. OSHA also regulates the control of radioactive materials in the workplace that are not regulated by the DOE or the NRC. OSHA's regulations for radiation protection can be found under 29 CFR Parts 1910 and 1926. OSHA is considering initiating revisions to its radiation protection standards. Current OSHA standards are based on ICRP 2 recommendations, and are no longer consistent with existing NRC or DOE requirements. Another reason for revision at this time relates to activities on guidelines following a radiological terrorism event.

Desired Outcome

OSHA regulations will be updated consistent with existing Radiation Protection Guidance to Federal Agencies for Occupational Exposure and consistent with the regulatory approach of NRC.

Plans for Interaction and Evaluation

NRC staff will continue to work with OSHA, through the ISCORS Federal Guidance Subcommittee, to provide comments for any revisions to OSHA's regulations to ensure consistency.

Resources

Estimated resources - 0.05 FTE each in FY04 and FY05, if needed.