POLICY ISSUE NOTATION VOTE

<u>July 27, 2006</u> <u>SECY-06-0168</u>

FOR: The Commissioners

FROM: Luis A. Reyes

Executive Director for Operations

<u>SUBJECT</u>: STAFF COMMENTS ON THE DRAFT RECOMMENDATIONS OF THE

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

PURPOSE:

To inform the Commission of the staff's review of the "Draft Recommendations of the International Commission on Radiological Protection" (ICRP).

BACKGROUND:

The primary mission of the ICRP is to advance the science of radiological protection by providing recommendations and guidance on all aspects of protection against ionizing radiation. ICRP offers its recommendations to regulatory and advisory agencies and provides advice intended to help management and professional staff with responsibilities for radiological protection. Toward that end, the ICRP regularly examines the status of its recommendations, and reviews scientific information to decide whether new recommendations are needed. In preparing its recommendations, ICRP considers the fundamental principles and quantitative bases upon which appropriate radiation protection measures can be established, while leaving to the various national regulatory authorities the responsibility of formulating the specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries. The ICRP recommendations form one of the principal bases for the U.S. Nuclear Regulatory Commission's (NRC) regulations and guidance for radiological protection. NRC participation in the review and consultation process is intended to influence the drafting and revision of ICRP recommendations at an early stage to ensure that the recommendations are supported by scientifically sound technical bases, are implementable in the United States, and provide a sound basis for U.S. regulations.

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The ICRP published the most recent comprehensive review of its recommendations in 1991 as ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection." Since then, the ICRP has issued 17 publications that provide additional guidance for controlling exposures from radiation sources, and the ICRP believes that a new set of recommendations is warranted. In so doing, the ICRP has the following primary objectives:

- Take account of the new biological and physical information and trends in setting radiation protection standards.
- Improve and streamline the presentation of the recommendations.
- Maintain as much stability in the recommendations as is consistent with the new scientific information.

The ICRP has prepared several iterations of conceptual ideas for proposed recommendations. The staff of the U.S. Nuclear Regulatory Commission (NRC) reviewed the previous version and provided its comments to the Commission in SECY 04-0223, dated November 26, 2004. Those comments were subsequently posted on the ICRP Web site (www.icrp.org) on January 7, 2005. The ICRP also prepared, and the staff reviewed, the following foundation documents, which provide the technical basis for the draft ICRP recommendations:

- "The Optimisation of Radiological Protection, Broadening the Process"
- "Assessing Dose to the Representative Individual for the Purpose of Radiation Protection of the Public"
- "Health Risks Attributable to Ionizing Radiation: A Summary of Judgements for the Purposes of Radiological Protection of Humans"
- "Basis for Dosimetric Quantities Used in Radiological Protection"
- "The Scope of Radiological Protection"

The ICRP posted the latest iteration of its recommendations on radiological protection on its Web site on June 7, 2006, and requested stakeholder comments by September 15, 2006. The ICRP will post stakeholder comments on its Web site as they are received, and will consider those comments in preparing the final draft. The ICRP intends to finalize its recommendations and release the related ICRP publication in 2007.

DISCUSSION:

The draft ICRP recommendations are intended to consolidate the advice developed since 1990. In particular, recent ICRP publications have recommended new dose assessment methodologies for the human respiratory tract (Publication 66) and alimentary tract (Publication 100, in press), use of new anatomical and physiological data (Publications 70 and 89), adoption of new radiation weighting factors (Publication 92), and usage of new age-dependent dose conversion coefficients (Publications 67, 69, 71, and 72). In addition, the draft ICRP recommendations include the following major features:

- Maintain the three fundamental principles of radiological protection (i.e., justification, optimization, and dose limitation), and clarify how they apply to radiation sources.
- Maintain the individual dose limits for effective and equivalent dose from all regulated sources that represent the maximum dose that regulatory authorities would accept in planned situations.

- Use the same conceptual approach to constrain doses in source-related protection in all types of exposure situations. The dose constraints are intended to quantify the most fundamental levels of protection for workers and the public from a single source in all situations.
- Complement limits and constraints with the requirement to optimize protection at the source.
- Update the understanding of the biology and physics of radiation exposure, and consequently update the radiation and tissue weighting factors in the dosimetric quantity effective dose.
- Provide a policy approach for radiological protection of non-human species.

The staff solicited comments on the draft ICRP recommendations from NRC program offices and interacted with the NRC's Advisory Committee on Nuclear Waste. The staff notified the Agreement and Non-Agreement States, as well as the Conference of Radiation Control Program Directors and the Organization of Agreement States, of the opportunity to provide comments directly to the ICRP. At the request of the Nuclear Energy Agency (NEA), the NRC staff, through the Interagency Steering Committee on Radiation Standards (ISCORS), will also host one of three regional workshops to review and discuss the ICRP recommendations. The NRC-NEA workshop will be held at the North Bethesda Conference Center on August 28–29, 2006. Participants from the United States, Canada, and Mexico will discuss how the recommendations can best be used to meet the health and safety needs of a broad group of stakeholders, and provide feedback to the ICRP. In addition, the staff will work with ISCORS to provide comments on the draft ICRP recommendations that reflect the common views of Federal agencies. Finally, the staff will participate in an NEA expert group to develop comments that reflect the common views of NEA and its members.

The staff believes that the latest draft ICRP recommendations are an improvement compared to the 2004 iteration. It is apparent that the ICRP addressed many, albeit not all, of the comments provided by the NRC staff. Considering the prior Commission guidance on ICRP activities, the staff has prepared the enclosed set of general and specific comments, in which the staff has identified the following issues that should be brought to the attention of the ICRP:

- The ICRP proposes to change the radiation and tissue weighting factors and nominal risk coefficients for cancer and hereditary disease. These changes may greatly impact regulations promulgated by regulatory authorities. Consequently, these changes must be based on the best available scientific information. However, this may not be the case for the tissue weighting factors and nominal risk coefficients. An analysis of Japanese A-bomb cancer incidence data using the new DS02 dosimetry system has not been completed. New risk estimates should not be adopted until this assessment is completed and published in a peer-reviewed journal for public review and scrutiny.
- The ICRP's attempt to clarify the meaning and use of dose constraint is an improvement, but further clarification is needed. The staff will request that the ICRP further clarify how constraints function within a radiation protection program (and optimization of protection for a source) to ensure adequate protection for an individual.

- The ICRP continues to advocate gender-averaged tissue weighting factors and numerical risk estimates. However, gender differences have been described in publications of the U.S. National Academies and the United Nations Scientific Committee on the Effects of Atomic Radiation. The staff will request that the ICRP clearly explain its rationale for this decision and how it accounts for gender differences in radiation sensitivity.
- The ICRP presents a number of recommendations related to small quantities of material, and the concepts of exemption and exclusion. As presented, the recommendations are inconsistent within the publication and could be misinterpreted. In particular, the staff believes that the present text inappropriately implies that exemption would only be appropriate when the individual dose is very low.
- The staff appreciates the ICRP's observations regarding the use of collective dose and
 the hypothetical estimates of health effects from very small doses. However, the general
 statements provided are not likely to impact practical regulation and risk communication
 unless additional guidance is provided regarding the appropriate and inappropriate uses
 of these concepts, and the boundaries within which the calculations are valid.
- In Paragraph 21, the ICRP states that its advice is aimed "principally at the regulatory authorities and operators that have responsibility for establishing protection standards, as well as their specialist advisors." However, in Section 6.3, "Exposure of Pregnant Patients," the ICRP addresses the issue termination of pregnancy. Such a discussion is beyond the scope of this document. The staff believes the ICRP should not present any numerical value that could be interpreted as the basis for terminating, or not terminating, a pregnancy. This discussion should be removed from the draft publication.
- The draft publication has not resolved the previous confusion between the concept of optimization of protection and the concept of a safety culture. Although an effective safety culture will contribute to continuing efforts to optimize protection, they are not equivalent. The staff believes that the underlying tenets of a safety culture and, in particular, the mindset of continually challenging the radiation protection activities to ensure that safety is being achieved, are also key components in the ongoing process of optimization. However, this relationship is not clearly articulated.
- The ICRP has not provided any policy or framework, proposed any assessment of
 exposures and pathways, nor provided any recommendations for protection of the
 environment. Consequently, Section 10, "Protection of the Environment," should be
 removed from the draft publication, and stakeholders should be afforded the opportunity
 to comment as the assessment framework is developed.

In conclusion, the staff believes that the draft 2006 recommendations do not yet achieve the ICRP's stated objective to consolidate, simplify, and elaborate on the previous set of recommendations published in 1991 as ICRP Publication 60. Furthermore, given that much of the text in the draft ICRP recommendations describes the current state of the system of radiological protection being implemented by many well-run radiation protection programs throughout the world, there is no compelling public health and safety argument for adopting the changes described in the draft ICRP recommendations, or for developing national regulations that would implement those recommendations at this time.

COMMITMENT:

Listed below are the actions or activities committed to by the staff in this paper:

- 1. NRC, through ISCORS, will host the NEA-sponsored North American regional workshop on August 28–29, 2006.
- 2. The staff will participate in the comment development efforts of ISCORS and NEA.
- 3. The staff will forward the enclosed comments to the ICRP before September 15, 2006.
- 4. The staff will continue to monitor the activities of the ICRP and will review subsequent documents as they become available.
- 5. The staff will continue to raise potential policy issues to the Commission.

RESOURCES:

The NRC staff has budgeted resources to review and evaluate the draft ICRP recommendations and supporting documentation as well as radiation protection recommendations of national organizations for the next two fiscal years. No new resources are requested.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection.

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Enclosure:

NRC Comments to ICRP