POLICY ISSUE
NOTATION VOTE

April 25, 2012 SECY-12-0064

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RECOMMENDATIONS FOR POLICY AND TECHNICAL DIRECTION TO REVISE RADIATION PROTECTION REGULATIONS AND GUIDANCE

PURPOSE:

The purpose of this paper is to summarize the staff's interactions with stakeholders as directed in Staff Requirement Memorandum (SRM)-SECY-08-0197, "Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection," and to request Commission approval of the staff's recommendations for policy and technical directions to revise the U.S. Nuclear Regulatory Commission's (NRC's) regulations and guidance for radiation protection.

SUMMARY:

The NRC staff has engaged a wide range of stakeholders on the potential issues associated with changes to radiation protection regulations in light of the recommendations of the International Commission on Radiological Protection (ICRP). The staff recommends that appropriate and scientifically justified changes be made in the current NRC Standards for Protection Against Ionizing Radiation, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, and other portions of the NRC regulatory framework. These changes would re-establish coherence in the basis of NRC regulations, provide consistency with the current estimates of attributed radiation risk, and increase alignment with international recommendations and the regulatory practices of our international counterparts. To achieve these objectives, the staff recommends the Commission approve development of policy and technical information to:

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1) update the regulations to recognize and use current scientific information, models, numerical values, and terminology for radiation exposure; 2) reduce the occupational dose limit for effective dose, lens of the eye, and the embryo/fetus of a declared pregnant female; and 3) consider in detail the benefits and impacts of increased use of the International System (SI) of units and the reporting of occupational exposure information by additional categories of licensees.

The staff recommended actions include the development of a detailed regulatory basis (previously referred to as technical basis) for proposed rulemaking. Although the recommended approach would not, in all cases, exactly align the NRC requirements with international recommendations and standards, they represent the staff's view of appropriate modifications based on the scientific information available on radiation risk, and the qualitative factors associated with increasing alignment with our international counterparts. The recommended directions would enhance the current requirements, particularly for those individuals who may receive occupational exposure at levels close to the regulatory limits for extended periods of time. Further, the staff recommends that current scientific information, models, numerical values, and terminology for radiation exposure serve as the basis for other parallel rulemakings, in particular the revision of 10 CFR Part 50, Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents."

The staff recommends that the Commission approve this approach recognizing that many of the recommendations would not be considered as a definition or redefinition of adequate protection under 10 CFR 50.109 or comparable backfit provisions in other NRC regulations. The backfit justification for a proposed rulemaking will have to rely upon both quantitative and qualitative measures similar to the approach taken by the Commission when it last approved major revisions to 10 CFR Part 20 more than 20 years ago. Additional stakeholder interactions will be needed to develop specific proposed language, guidance, and impact assessments in order to complete a regulatory basis for revision of 10 CFR Part 20 and 10 CFR Part 50, Appendix I.

BACKGROUND:

On April 12, 2002, in SRM-SECY-01-0148, "Processes for Revision of 10 CFR Part 20 Regarding Adoption of International Commission Radiation Protection (ICRP) Recommendations on Occupational Dose Limits and Dosimetric Models and Parameters," the Commission approved the staff's recommendation to not initiate consideration of changes to 10 CFR Part 20 until the ICRP had completed its update of the system of radiological protection. ICRP Publication 103 (December 2007) contained the revised recommendations, which reflect an evolution from the previous recommendations contained in ICRP Publication 60 in 1990, and ICRP Publication 26 in 1977.

10 CFR Part 20 provides the fundamental radiation protection regulatory requirements for NRC licensees. The Agreement States have certain requirements (e.g., dose limits) that are essentially identical to 10 CFR Part 20 for their licensees. The most recent rulemaking to incorporate the recommendations of the ICRP into 10 CFR Part 20 was completed in 1991 (56 FR 23360) and was based primarily on the 1977 recommendations contained in ICRP Publication 26. The final rule also reflected a clarification made by the ICRP in 1985 (Statement contained in ICRP Publication 45) that 100 mrem (1 mSv) was the recommended principal limit

for members of the public. The revised recommendations for occupational exposure limits, contained in ICRP Publication 60, could not be considered in the final rule because those recommendations were not within the range of options for public comment during the rulemaking development process. Other than for 10 CFR Part 20, and its conforming changes, the 1991 rulemaking did not incorporate the recommendations of ICRP for the remainder of the NRC regulatory framework (e.g. 10 CFR Parts 32, 50, 51, 61, and 72). In SRM-SECY-01-0148, the Commission directed that the staff should continue to consider and grant, as appropriate, licensee requests to use revised internal dosimetry models on a case-by-case basis. As such, the basis for the current NRC regulatory framework is a mixture of radiological standards, concepts and quantities ranging from the 1958 recommendations contained in ICRP Publication 1 to the modeling and numeric values of the 1990 recommendations in ICRP Publication 60.

In SRM-SECY-08-0197, April 2, 2009, the Commission approved the staff's recommendation to begin engagement with stakeholders and interested parties to initiate development of the technical basis (now referred to as regulatory basis) for possible revision of the NRC's radiation protection regulations, as appropriate and where scientifically justified, to achieve greater alignment with the 2007 ICRP recommendations. The Commission also directed that the staff continue its participation in various national and international forums, recognizing that these efforts and the evaluation of alignment with ICRP Publication 103: 1) will inform NRC where changes to regulations may be merited; 2) will help establish a technical basis for instances where exceptions to ICRP Publication 103 continue to be appropriate; and, 3) will result in continued high assurance that NRC's regulatory framework for radiation protection is sound.

DISCUSSION:

Following the Commission's direction in SRM-SECY-08-0197, the NRC staff has engaged with a wide range of stakeholders, supported assessments of impacts of the implementation of ICRP's recommendations in other countries, and participated in national and international forums. The staff participated in the revision of the International Basic Safety Standards by the International Atomic Energy Agency (IAEA), and observed the ongoing revision of the Euratom Basic Safety Standards Directive in the European Union. In both instances, the proposed revisions focus on aligning requirements with the current ICRP recommendations. These efforts have led to the identification of policy issues where direction from the Commission is needed to guide the development of the regulatory basis for a general revision of NRC's radiation protection regulations, if supported by the Commission. The discussion sections that follow provide a summary of the staff's interactions and the policy and technical issues where decisions are needed on how to proceed.

1) Update Regulations:

Radiation Risk:

Central to any discussion of possible changes to the NRC radiation protection framework is understanding of radiation risk, and the extent to which changes in that understanding suggest a need for change. At the present time, the basis for the NRC regulations is a mixture of risk information ranging from 1958 to 1990. The majority of the provisions in 10 CFR Part 20 are based on an assumed radiation risk of 1.25×10^{-4} per rem (1.25×10^{-2} per Sv), and considered cancer mortality and risk of heritable diseases. Since 1977, there have been a number of national and international re-examinations of radiation risk, and radiation risk modeling. The

overall radiation risk, used to support the 1990 recommendations of ICRP, and generally reaffirmed with the 2007 recommendations, is a nominal value of 5×10^{-4} per rem (5×10^{-2} per Sv). Assessments have also continued to examine the model to be used for estimating risk at the low dose and dose rates experienced in public and occupational exposures. The ICRP concluded that a linear, non-threshold approach remained a prudent basis for practical purposes of radiation protection. The same conclusion has been drawn by the National Academy of Sciences (NAS) in the report on the Biological Effects of Ionizing Radiation (BEIR), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the National Council on Radiation Protection and Measurements (NCRP).

The recommendations of ICRP from 1977 to 1990 and on to 2007 also represent an evolution of the underlying decision basis for selecting the dose limits. The 2007 recommendations reflect consideration of morbidity as well as mortality, and a risk informed selection of a recommended dose limit aimed at controlling occupational exposure over the working life of an individual to less than 100 rem (1 Sv). Of note is the fact that, while the overall estimate of risk remained essentially the same, the contribution of heritable diseases decreased significantly between 1990 and 2007. A more detailed review of the radiation risk values and the basis for selection of dose limits is provided in Enclosure 1.

In April 2011, the ICRP released a statement addressing non-cancer effects, and recommended a change in the dose limit for lens of the eye based on a significantly lower threshold for the induction of cataracts. The threshold for cataracts is now considered to be 50 rad (500 mGy). The statement indicated that other non-cancer effects, including stroke and cardiovascular disease, also were being shown to have a significantly lower threshold of induction, but did not suggest changes to the limits for effective dose. As a result the ICRP recommended an equivalent dose limit for the lens of the eye of 2 rem (20 mSv) in a year, averaged over defined periods of 5 years, with no single year exceeding 5 rem (50 mSv). The ICRP publication which supports the April 2011 statement has not yet been published.

The NRC staff has concluded that the changes in radiation risk, and the methodologies for recommending dose limits, provide a sufficient risk informed scientific basis to justify revisions to the regulatory framework for radiation protection consistent with the current understanding of radiation risk.

Stakeholder Dialogue and Feedback:

The NRC staff has engaged a wide range of stakeholders on the broad issues of possible revision of the radiation protection framework. Three *Federal Register* Notices (FRN's) have been issued, soliciting feedback and comments (74 FR 32198, July 7, 2009; 75 FR 59160, September 27, 2010; and 76 FR 53847, August 30, 2011). Presentations and discussions have taken place with a variety of professional societies, licensee organizations, public interest groups, and the States. In the fall of 2010, the staff conducted a series of facilitated round table workshops in Washington, D.C., Los Angeles, California, and Houston, Texas. Each workshop included representatives from a broad range of users of radioactive material. In addition, each workshop provided a more focused opportunity for certain segments of stakeholders to have a more complete representation in the discussion. The workshop in Washington, D.C. included a focus on the nuclear power industry, and other Federal agencies. The Los Angeles workshop included a focus on medical uses of radiation, and the Houston workshop included a focus on industrial uses. These workshops effectively provided a broad spectrum of stakeholders the

opportunity to discuss the various technical issues with each other, and with the NRC staff. Transcripts of each workshop, and all of the written comments received in response to the FRN's, are publicly available.

At a high level, the response of most stakeholders, including various types of licensees, was that changes should be made to reflect the current dose calculation methodology and terminology. At the same time, these stakeholders did not support changes to dose limits and As Low As Reasonably Achievable (ALARA) provisions. Typical viewpoints were that the changes in risk did not warrant a change in limits, that changes would result in unacceptable impacts to licensed uses, and that the different types of sources and uses in the United States should be justification for different limits. When representatives of licensed activities expressed general concerns with the possible changes to the regulatory requirements, the staff attempted to gain further insights into the details of the reasons for their positions. Unfortunately, requests to provide specific supporting rationale did not result in significant additional information being provided to the NRC staff. A more detailed summary of the staff interactions with stakeholders is provided in Enclosure 2. The staff assessment for each of the technical issues and stakeholder feedback is provided in Enclosure 3. The staff does not believe that the differences in sources and uses in the United States justify different limits based on radiation risk (*see* Enclosure 3, Section 2).

In response to SRM-SECY-08-0197, the staff has undertaken several efforts to examine the possible impacts of changing 10 CFR Part 20 and the basis of 10 CFR Part 50, Appendix I design objectives. With respect to 10 CFR Part 20, the Commission directed the staff to examine how lower dose limits have affected the medical and industrial sectors in countries that have implemented them. Enclosure 4 provides information developed to date by the NRC staff. The staff collaborated with the Nuclear Energy Agency in conducting a survey of representative European, North American, and Asian countries to obtain available information from a cross section of countries that implemented ICRP Publication 60 recommendations and are now considering implementation of ICRP Publication 103 recommendations. With respect to 10 CFR Part 50, Appendix I, a summary of the technical issues and stakeholder feedback is provided in Enclosure 3, Section 9. Additional information on the background and justification of a proposed revision of 10 CFR Part 50, Appendix I was provided in Enclosure 3 of SECY-08-0197.

State Perspectives:

The NRC staff has engaged the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors (CRCPD) throughout the process of soliciting positions and information. Representatives of these organizations actively participated in each of the facilitated round table workshops. A pre-decisional draft of this paper was shared with the States through an All State Radiation Control Program Director letter (RCPD-12-006, March 6, 2012), and a conference call was held on March 27, 2012. Representatives of 12 different state organizations participated in the conference call. These individuals expressed general support for the NRC staff recommendations in this paper, asked a number of questions regarding details of staff positions and implementation, and engaged in a discussion of how various technical issues could be pursued in the next phase of the process. The States noted that much of the impact in their programs (e.g. changes to State regulations and changes to the radiation protection program of licensees and registrants) will be in the area of machine produced radiation, and suggested that the impact on the Agreement State programs for byproduct materials would not be as significant. State representatives also suggested possible next steps

for engaging their licensees and registrant groups in the discussion of implementation and impacts of possible regulatory changes if the process moves forward.

Methodology and Terminology for Dose Assessment:

Since the 1977 ICRP recommendations, the methodology for dose assessment has changed, as the models and specific factors in the calculation of dose were modified. The terminology also changed, reflecting the change in methodology. Nevertheless, the underlying approach, allowing the summation of doses from internal and external exposures, has remained the same.

Stakeholder feedback generally supported the NRC consistently incorporating the latest scientific information and modeling. Some stakeholders noted the difficulty caused by the difference in the calculations required to demonstrate compliance with different portions of the regulations. Stakeholders, while supporting use of the new terms, also expressed concern about the impacts of updating procedures, records, reports, and training to align with new requirements.

Recommendation:

The staff recommends that the regulatory framework be updated to reflect the new terminology and dose calculation methodologies, to align with the current national and international scientific approach for estimating radiation exposure and risk, and eliminate the differences in radiological standards, concepts and quantities currently found in the NRC regulatory framework. Further, the staff recommends that a rulemaking not be initiated to reflect these changes until all of the dose coefficients and other supporting information for ICRP 103 are available, so that a single, comprehensive change can be made to the relevant provisions and appendices of 10 CFR Part 20 and to the provisions of the 10 CFR Part 50, Appendix I design objectives. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 1.

2) Reduce Dose Limits:

Limits for Occupational Total Effective Dose Equivalent:

The area of greatest discussion, and controversy, is the possibility of changes to the occupational dose limits. The current NRC regulations differ from international recommendations and standards, and the basis for these regulations does not reflect the current national and international estimates of risk. Most stakeholders were opposed to any change in the dose limit, although some stakeholders also indicated that the differences have led to transboundary issues with the movement of workers to and from the United States. These stakeholders indicated that a change in the limit is not necessary, could have significant impacts on licensed activities, could impact the delivery of health care, could increase the rate of non-compliance, and is not appropriate because sources and uses in the United States are different (e.g., larger activity sources, and a greater number of procedures) from many other nations.

The vast majority of occupational exposures in the U.S. are less than the international recommendations and standards, not because of the value of the limit, but because of the application of the ALARA principle. At the same time, the available data shows that a limited

number of individuals continue to receive occupational exposures close to the limit each year. Thus, while the regulations provide for adequate protection, the dose limits do not ensure that a particular individual would not exceed the 100 rem (1 Sv) value recommended by the ICRP and NCRP over an occupational life time.

Recommendation:

The staff believes that it is appropriate, and scientifically justified, to recommend that occupational exposures that are near the current dose limit be reduced. Although recognizing the strong opposition by many stakeholders, the staff recommends that a reduction in the occupational limit to 2 rem (20 mSv) per year be explored in greater detail, including the mechanisms that would be available to provide some flexibility for licensees to request a higher limit under specified conditions. The recommended approach is the most straight forward performance based approach for eliminating exposures that are above the internationally recommended values, and which present an increased risk should they be received over many years. The approach would foster global consistency, which facilitates the transboundary employment of workers. Further, the staff does not believe that differences in source strength, uses of material, or suggestions of non-compliance provide a sufficient justification for not reducing the limit. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 2.

Limits for Lens of the Eye:

A statement by the ICRP in April 2011, recommended a reduction in the annual limit for the lens of the eye (*see* Enclosure 3, Section 3). The recommendation was based on the compilation of scientific evidence that radiation induces cataracts at lower cumulative dose levels than previously estimated.

NRC's stakeholders expressed a range of views on the options and rationale. In a number of cases, stakeholders agreed that the limit should be reduced from the present value of 15 rem (150 mSv) per year, but concerns were raised about the value recommended by ICRP (2 rem (20 mSv) per year averaged over 10 years with no more than 5 rem (50 mSv) in any one year). Concerns were also raised about the comparability of the endpoint, namely a cataract in the eye, versus the morbidity and mortality from cancer. Some supported this concern by noting that lens replacement for cataracts is a routine procedure, and a significant percentage of the population will experience cataracts as they age for reasons unrelated to occupational radiation exposure. Therefore, some stakeholders suggested that a reduction to 5 rem (50 mSv) in a year might be more appropriate than the ICRP recommendation. This view was also supported by stakeholders who pointed out that the limit for the lens of the eye should not be less than the limit for whole body exposure.

Recommendation:

The staff believes that it is appropriate, and scientifically justified, to recommend that the impacts of a reduction in the dose limit for the lens of the eye of either 5 rem (50 mSv) or 2 rem (20 mSv) be explored in greater detail, and that the dialogue continue on how the prevention of cataracts should be viewed in comparison with the potential induction of cancer and other adverse impacts. The approach would move towards increasing alignment, but would not

necessarily result in adoption of the ICRP recommendations. Further discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 3.

Limits for Exposure of an Embryo/Fetus:

The ICRP has aligned its recommendation for limiting dose to an Embryo or Fetus of an occupationally exposed female to the numerical value of the public dose limit.

Feedback was mixed from stakeholders on possible changes in the provisions. Many licensees suggested that they had no problems complying with the present requirements. Furthermore, many licensees stated that their response to a declaration of pregnancy was to accommodate the individual in such a way that there was essentially no occupational exposure for the duration of the pregnancy. On the other hand, some stakeholders from the medical community expressed a concern that a change in the limit might result in female physicians making a decision not to declare their pregnancy, rather than have their work or medical training impacted. Other stakeholders provided specific examples of working situations in which a change might cause an impact. In addition, some stakeholders have expressed the view that the 100 mrem (1 mSv) value should be applied to the entire gestation period, in order to assure adequate protection.

Recommendation:

The staff believes that it is appropriate, and scientifically justified, to recommend that a change in the dose limit for the embryo/fetus to 100 mrem (1 mSv) be explored in detail. Such an approach would more clearly align the regulatory requirements with the scientific information available that the embryo/fetus is more sensitive to radiation, and more clearly align the NRC regulations to ICRP recommendations. The option of applying the limit over the entire gestation period, or only to the portion of time following declaration, would need to be explored in greater detail. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 4.

ALARA Planning:

The 2007 ICRP recommendations add emphasis to optimization, and the use of constraints in planning for radiation protection. Stakeholders generally stated that they do planning for ALARA as part of their radiation protection programs, and that a variety of values are used in that planning process. When asked about adding a requirement for constraints or planning values, licensees expressed significant concern that such a value would become a de facto limit, and cited examples of similar concepts that have been treated as limits in determining compliance. Others proffered a view that a set of requirements to establish and use planning values could be a more acceptable approach than reducing the dose limit, depending on the wording of such a requirement.

Recommendation:

The staff does not believe that it is appropriate to recommend additional requirements on ALARA, based on a conclusion that such requirements would be unnecessarily prescriptive in nature, and would not ensure a reduction in individual exposures. Nevertheless, the staff believes that there may be reasons to update regulatory guidance to provide additional

examples of mechanisms that would be acceptable in the development and implementation of radiation protection programs. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 5.

3) Issues for Further Consideration:

Protection of the Environment:

The ICRP recommendations in Publication 103 discuss protection of the environment, and indicate the ongoing work to develop a framework to assess exposures in the environment to reference animals and plants. This activity is ongoing in the ICRP, and has been aimed primarily on the development of tools for dose assessment. The topic was not initially presented as a formal topic of discussion with stakeholders, but some discussions did take place in a number of forums. Feedback generally affirmed the currently stated Commission position that additional regulatory standards were not necessary.

The staff continues to believe that there is no need for additional NRC requirements in this area. The staff recommends that NRC continue to monitor, and interact with the various international organizations in developing tools and methodologies for assessment of doses in the environment. Such work could be useful to provide validated approaches that could be used within the existing regulatory structure in the United States under the National Environmental Policy Act. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 6.

Units of Radiation Exposure and Dose:

The current NRC metrication policy provides for the use of both traditional units (rad, rem, curie) and SI units (Gray, Sievert, Becqueral). 10 CFR Part 20 was published before the current metrication policy, and lists the SI units in parenthesis. On a number of occasions during the stakeholder dialogues, staff was asked if this was the time to move to using the SI units. Stakeholders noted that this was another terminology issue where the NRC, and the United States more generally, are not aligned with the rest of the world, and further suggested that a move to adopt the SI units would facilitate discussions across national borders. For example, the Health Physics Society issued a final Position Statement in February 2012 on the "Exclusive Uses of SI Units to Express Radiological Quantities (see *http://hps.org/documents/SIunits_ps023-0.pdf*) stating that "…the continued use of traditional units to express radiological quantities in the United States … can have significant repercussions with regard to effective response to radiation emergencies…". Stakeholders also noted that the use of SI is now routine, and in fact required, in the scientific literature, and that licensees whose interests are international must, from a business perspective, use the SI units.

Recognizing the interest in the stakeholder communities, the staff recommends that the implications, benefits, and costs of aligning to the NRC metrication policy be explored. The staff recognizes that such a change would not directly contribute to public health and safety, and that uncertainty in the units being used can be problematic. A more detailed assessment, and stakeholder engagement, will be necessary to provide a recommendation to the Commission. Such considerations will require close interaction with other Federal agencies as well as the States. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 7.

Reporting of Occupational Exposure:

The staff has experienced significant difficulty in developing reasonable assessments of the impacts of reducing the occupational dose limits for some segments of licensed use. This difficulty is partially caused by the fact that only certain categories of NRC licensees are currently required to report occupational exposure information. Agreement States licensees, for categories such as industrial radiography, are subject to the reporting requirements of those States, and do not necessarily submit an annual report that would be maintained in the NRC's Radiation Exposure Information and Reporting System (REIRS) database. In some cases, the NRC has reports that have voluntarily been provided to REIRS. A more serious issue is that there are categories of licensees, particularly involving medical use, where there is no requirement for reporting of occupational exposure. As a result, the issue of reporting involves both the question of who needs to report, and how to effectively integrate the reporting from licensees in the NRC and Agreement States programs.

The staff recommends that a more detailed examination of the implications, benefits, and costs of requiring additional categories to report exposures be pursued. Such information would be useful in assessments of impact for regulations. More importantly such information could constitute a source of data for ongoing use by the NRC and Agreement States in inspection, enforcement, and incident response activities. The examination would consider the increased use of the existing REIRS database as a national occupational exposure database, with information available for NRC and Agreement States. One advantage of such a system would be in correlating exposures of an individual from different licensee organizations. At present there is no mechanism for the NRC, or an Agreement State, to ascertain independently if an individual is exceeding the dose limits as a result of exposure at multiple licensee facilities or sites. Such considerations will require close interaction with other Federal agencies as well as the States. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 8.

10 CFR Part 50, Appendix I:

Over the past decade, there have been discussions with stakeholders and interested parties about updating the basis of the ALARA effluent guidelines of 10 CFR Part 50, Appendix I, and supporting guidance documents to be consistent with the dose methodology used in 10 CFR Part 20. Appendix I was not revised as part of the 10 CFR Part 20 revision in 1991, and continues to require calculations based upon the methodology of ICRP Publication 2, which was issued in 1959. Issues have been raised on applicable radiation protection requirements in light of new applications for early site permits, design certifications, and combined licenses submitted under 10 CFR Part 52. Of course new applications for construction permits and operating licenses for small modular reactors may be filed under 10 CFR Part 50.

Stakeholder feedback was specifically encouraged on this topic during the Washington, D.C. workshop. The nuclear power industry pointed out the inconsistencies of approach between 10 CFR Part 20, and 10 CFR Part 50, Appendix I for ALARA in light-water-cooled nuclear power reactor effluents. As a result, licensees have indicated that there is a substantial impact from having to use different dose calculation methodologies for demonstrating compliance with different portions of the regulations. The discussions also covered a number of other topics in a possible revision that are not specific to alignment with international recommendations, as discussed in Enclosure 3 of SECY-08-0197. Enclosure 3 of that SECY paper outlined

ramifications on regulatory programs and potential impacts on stakeholders and members of the public that would need to be evaluated in the development of a revised regulatory basis. Other stakeholders raised concerns about the revision "relaxing" or appearing to relax the requirements in some manner.

The staff recommends that work be initiated to develop the regulatory basis for a revision of 10 CFR Part 50, Appendix I to address the set of issues that have been identified and are unique to Appendix I requirements. The staff also recommends that the revision of Part 50, Appendix I reflect alignment with the approach of 10 CFR Part 20, utilizing the new terminology and dose calculation methodologies of ICRP Publication 103 recommendations.

The staff recommends that this effort be initiated on a parallel track with the potential revisions to 10 CFR Part 20 and managed under a separate rulemaking due to the unique challenges discussed in SECY-08-0197. For example, the staff recognizes the complexity of the proposed revision to guidance documents and ramifications on the implementation of the Reactor Oversight Process. The discussion of background, stakeholder feedback, and staff analysis is found in Enclosure 3, Section 9.

Policy Options:

The staff has developed several options for Commission consideration, based on the results of the stakeholder dialogue and technical basis development to date. The first option is to make no change to the existing regulatory framework of 10 CFR Part 20 and 10 CFR Part 50, Appendix I. The second option is to develop the regulatory basis to update only certain portions of the regulations, specific to the calculation of exposure, while keeping all of the dose limits in 10 CFR Part 20 as currently specified. The third option is to continue interaction with stakeholders to develop the regulatory basis for specific proposed rule language, and associated guidance, to increase alignment with international recommendations and standards.

Option 1: Status Quo – No changes to 10 CFR Part 20 or 10 CFR Part 50, Appendix I

The status quo option would result in no further development of possible changes to NRC's radiation protection framework in 10 CFR Part 20 and 10 CFR Part 50, Appendix I. Under this option, no additional resources would be expended at this time to increase the alignment with current scientific information, international recommendations, and the standards adopted by the Department of Energy for the defense nuclear complex and by many other nations, IAEA, and NEA. Selection of this option would be premised on a finding that the current regulations continue to provide adequate protection of public health and safety, are well understood by licensees, and that the impacts of changing the regulatory framework are not justified by the benefits. Under this option, the staff would continue to monitor the experiences gained in implementing ICRP 103 in other programs and countries.

The staff does not recommend this option because the bases for the existing NRC regulatory radiation protection framework in 10 CFR Part 20 and 10 CFR Part 50, Appendix I are a series of radiological standards, concepts and quantities ranging from the 1958 recommendations contained in ICRP Publication 1 to the modeling and numeric values from the 1990 recommendations in ICRP Publication 60, that are not aligned with the current international recommendations to estimating radiation exposure and risk. Although staff supports a finding that the current radiation protection framework provides adequate protection, the terminology,

conceptual basis, and methodology that support this framework are falling further behind the rest of the world. Further, the staff notes that the nuclear industry has stated a strong preference that NRC should update the regulatory structure of 10 CFR Part 50, Appendix I to be consistent with 10 CFR Part 20.

Option 2: Develop Regulatory Basis for Limited Revision of 10 CFR Part 20 Dosimetry Basis and Parallel Alignment of 10 CFR Part 50, Appendix I

Under this option, the staff would develop the regulatory basis to support a revision of certain provisions of 10 CFR Part 20, including the definitions of radiation weighting factors, tissue weighting factors, and 10 CFR Part 20, Appendix B Tables 1, 2, and 3, to align with the most recent methodology and terminology for dose assessment. The staff would continue to work with other Federal agencies, and the ICRP, to complete the calculation of dose coefficients based on the latest recommendations. In a parallel effort, the staff would initiate the development of the regulatory basis for revision of 10 CFR Part 50, Appendix I to align with the update of 10 CFR Part 20, and address the unique set of issues that are not directly connected with 10 CFR Part 20.

The content and scope of this option was supported by many stakeholders during the various discussions and forums. This option would move, to a limited extent, in the direction of increasing alignment with international recommendations and standards. The resulting rules, if promulgated by the NRC, would foster greater consistency in the scientific approach to dose assessment and would, in some cases, simplify compliance by licensees who are currently required to demonstrate compliance with different provisions of the NRC regulations with completely different assessment methods, or teach new employees earlier terms and methods that are receiving less attention in university curricula.

With respect to backfitting issues, most material licensees are not subject to backfitting requirements, so issuance of the rule has no special significance from the standpoint of backfitting for those licensees. For materials licensees subject to backfitting protection under §§ 70.62, 72.62 and 76.76, the rulemaking may constitute backfitting and therefore, may have to meet the requirements of the applicable backfitting provisions. The rule, if applied to current holders of operating licenses under 10 CFR Part 50, will likely constitute backfitting and will have to meet the requirements of the Backfit Rule. In addition, if the rule applies to holders of combined licenses under 10 CFR Part 52 whose licenses were issued before the final rule, then the rule will likely require justification under the issue finality provisions of 10 CFR 52.63 (and any applicable issue finality provisions in a referenced design certification rule, if applicable), for design-related matters involving 10 CFR Part 20 requirements. The staff has not determined whether the rule should apply to current design certifications based on assessments of the regulatory basis to date; if it does, then the rule will likely require justification under the issue finality provisions of 10 CFR 52.63 and Paragraph VIII of each of the current design certification rules, as identified in the appendices of 10 CFR Part 52. Backfitting and issue finality is discussed in further detail in Enclosure 3, Section 10 for all classes of licensees and regulated entities.

The staff does not recommend this option because, although a viable option, it would not be a complete, consistent, and coherent response to the available science and risk information under ICRP Publication 103 recommendations. The result of this option would be to update the approach for demonstrating compliance to the latest scientific information, but would leave in

place the occupational dose limits which are based on older science and risk information. Under the existing Commission policy (SRM-SECY-01-0148), a licensee may request use of the latest scientific information. However, the case by case approach is inefficient in its implementation as it regulates by exemptions and license conditions and does not offer the opportunity to standardize the regulatory process for licensees and NRC staff.

Option 3: Develop Regulatory Basis for Greater Alignment of 10 CFR Part 20 Dosimetry and Limits and Parallel Alignment of 10 CFR Part 50, Appendix I

Under this option, the staff would develop the regulatory basis for a revision of certain provisions of 10 CFR Part 20 occupational dose limits. As with Option 2, the staff would develop the basis for revision of the definitions of radiation weighting factors, tissue weighting factors, and 10 CFR Part 20, Appendix B Tables 1, 2, and 3. The staff would also explore the merits of a number of related topics, including the use of SI units and reporting of occupational exposure by additional categories of licensees. The staff would initiate work with stakeholders to develop possible rule text, guidance, and the supporting regulatory analysis material for a proposed rulemaking. The staff would, as in Option 2, initiate the parallel development of the regulatory basis for revision of 10 CFR Part 50, Appendix I to align with the update of 10 CFR Part 20, and address the unique set of issues that are not directly connected with 10 CFR Part 20.

This option includes elements that were supported by stakeholders, and elements that were opposed by stakeholders. Nevertheless, the staff believes it is appropriate, and scientifically justified, to develop the detailed draft language for changes that would achieve a greater degree of alignment with current scientific information, and with international recommendations and standards. The staff is presenting the path forward for the technical issues as a set, although conceptually each issue can be included or excluded based on the merits of each issue. The staff's recommendation to move forward with development of the entire set is intended to minimize disparities in the NRC's response to the current scientific information to the extent justified by the rationale for the revisions.

The staff will consider the requirements of applicable backfitting requirements in 10 CFR Chapter I, including applicable issue finality provisions in 10 CFR Part 52 in developing any proposed rules. Based on staff's analysis to date, portions of the rule may be justified under the adequate protection exceptions in the applicable backfitting provisions (including comparable adequate protection criteria in the issue finality provisions of 10 CFR Part 52), while other portions may be justified as substantial increases in protection to public health and safety which are cost-justified, using both quantitative and qualitative arguments. The discussion of backfitting is found in Enclosure 3, Section 10 for all classes of licensees and regulated entities.

IMPLEMENTATION:

There are several factors, particularly the timeline for the development of dose conversion factors, which result in a regulatory basis under Options 2 or 3 not being complete before the end of 2015. The staff notes that the development of the proposed and final rules, and provisions for a period of time before final implementation, would likely result in an effective date of the revisions to these regulations of 2020 or later. The staff's recommended approach, described in Option 3 above, would utilize the relatively modest resources currently budgeted to systematically engage stakeholders on the development of the regulatory basis, and draft rule

text and associated guidance for Commission consideration in about 2016. The next update to the ICRP recommendations is not expected to occur before 2020.

COMMITMENTS:

The staff proposes to engage stakeholders and interested parties on the specific resolution of technical issues, and continue development of the regulatory basis and regulatory analysis information during Fiscal Year (FY) 2012 through FY 2015 for revision of 10 CFR Part 20. Parallel efforts would develop the regulatory basis for revision of 10 CFR Part 50, Appendix I. Upon completion of the regulatory basis, the staff would initiate rulemakings to prepare the proposed rules for Commission consideration.

RECOMMENDATIONS:

The staff recommends that the Commission approve Option 3. The staff will continue development of a regulatory basis and engage in stakeholder outreach on possible rule text, guidance, benefits, and impacts for proposed rules. The staff will develop and provide to the Commission proposed rules for 10 CFR Part 20 and 10 CFR Part 50, Appendix I, following completion of their respective regulatory basis.

The staff recommends that this paper, and the enclosures, be made publicly available to facilitate discussions with stakeholders and interested parties. The staff also recommends that, if approved, these activities be pursued as a Commission-directed, medium-priority rulemaking.

RESOURCES:

Limited resources are currently included in the staff's business line budgets for FY 2012 through FY 2014 to implement the staff's recommended option to continue stakeholder and interested party interactions and regulatory basis development. For 10 CFR Part 20, approximately 3.6 Full Time Equivalent (FTE) and $400K are budgeted in FY 2013. For 10 CFR Part 50, Appendix I, approximately 1.9 FTE and $60K are budgeted in FY 2013. A more detailed breakdown of resources by business line, and preliminary estimates of resources for future years are provided in Enclosure 5. The staff will address the budget for this activity in future budget submittals using the PBPM process once the Commission has issued its SRM for this paper.

COORDINATION:

The Office of the General Counsel has reviewed this paper and its enclosures and has no legal objection. The Office of the Chief Financial Officer reviewed this Commission Paper for resource implications and has no objections. Informational briefings were held with the Advisory Committee on the Medical Use of Isotopes and with the Advisory Committee on Reactor Safeguards.

/RA by Michael F. Weber for/

R. W. Borchardt,
Executive Director
for Operations

Enclosures:
1. Radiation Risk
2. Summary of Stakeholder Interactions
3. Assessment of Technical Issues and Feedback
4. Examination of National and International Impacts of Adoption of ICRP Recommendations
5. Resource Estimates

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