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

Radiation Risk

The purpose of considering amendments to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 is to modify the U. S. Nuclear Regulatory Commission's (NRC's) radiation protection standards to reflect developments in the scientific knowledge underlying radiation protection that have occurred over the last 30 years. These developments not only include scientific information on radionuclide uptake and metabolism, but include an increased understanding of the inherent health risks associated with radiation exposure.

The current 10 CFR Part 20 is based upon the radiation risk estimates from the 1970's, as reflected in the International Commission on Radiological Protection (ICRP) recommendations in 1977. The radiation risk was estimated to be 1.25×10^{-4} per rem (1.25×10^{-2} per Sv), and considered cancer mortality and risks of heritable disease.

Evolution of Risk Estimates:

Following its 1987 meeting in Como, Italy, the ICRP issued a statement that reviewed the existing estimates of the biological risks of ionizing radiation and the preliminary data from the reanalysis of the Hiroshima-Nagasaki atomic bomb follow-up studies. Reanalysis of these data indicated that the risks from gamma radiation are approximately a factor of 2 higher than previous estimates for the general population and are also higher, but by a smaller factor, for workers. The ICRP concluded in 1987 that this information was not considered sufficient at the time to warrant a change in the dose limits for occupational exposure. The ICRP also noted that the potential higher risks indicated by the reanalysis of the atomic bomb data should not be a major consideration as the dose limits should not be of primary importance in controlling doses if the principle of keeping radiation exposures "As Low As is Reasonably Achievable" (ALARA) is being practiced. This position has since been modified by the ICRP 1990 recommendations.

The 1988 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) contains information on the health risks of ionizing radiation determined from a reevaluation of the data on the survivors of the Hiroshima-Nagasaki atomic bombings. Based on these data, the radiation risk at high doses and high dose rates was estimated to be 7.1×10^{-4} fatal health effects per rad (7.1×10^{-2} per Sv). For estimating the risk from radiation doses below 100 rads (1 Gy), UNSCEAR recommended that a dose rate reduction factor be applied to account for the reduced effectiveness of lower doses and lower dose rates. This would lead to an estimated risk between (0.7 and 3.5) $\times 10^{-4}$ health effects per rad ((0.7 - 3.5) $\times 10^{-2}$ per Sv) for low doses such as those encountered in routine occupational exposure. The fatal cancer risk as estimated by the 1988 UNSCEAR report for low doses are between 1.7 times lower to 2.8 times greater than the 1977 ICRP estimate.

The 1990 report of the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation (BEIR-V) was a comprehensive reevaluation of the health risks of radiation exposure based upon the revised dose estimates for the survivors of the Hiroshima-Nagasaki atomic bombings. The BEIR-V report, like the 1988 UNSCEAR report, indicates that a

reduction factor should be applied to the risk estimates derived from high doses and dose rates in order to apply them to low dose and low dose situations. Assuming a factor of 2 reduction, the BEIR-V would give a lifetime risk of a radiation-induced cancer fatality of about 4×10^{-4} fatal cancers per rem (4×10^{-2} per Sv) for workers and 5×10^{-4} fatal cancers per rem (5×10^{-2} per Sv) for the general population, the higher value for the public being associated with the higher sensitivity and the longer period of elevated risk associated with the younger ages present in the general population. This value is four times as large as the estimate in the 1977 ICRP recommendations.

The 1990 ICRP Recommendations contain another comprehensive reevaluation of the health risks of radiation exposure. The ICRP concluded, after reviewing the available experimental information on dose-response relationships and the influence of dose and dose rate, that the most probable response is linear quadratic in form for low Linear Energy Transfer (LET) radiation. The linear coefficient at low doses or low dose rates is obtained from the high dose, high dose rate estimates of risk. Averaging estimates of probability for total fatal cancer from the 1988 UNSCEAR report and the BEIR V report with estimates derived by ICRP, the average nominal risk acute high dose exposure is 10×10^{-4} fatal cancers per rem (10×10^{-2} per Sv). The ICRP applied a dose and dose rate effectiveness factor of 2 to yield a nominal value of 5×10^{-4} per rem (5×10^{-2} per Sv) for the probability of induced fatal cancer in a population of all ages. This value is four times as large as the risk estimate contained in the 1977 ICRP recommendations. A smaller value would be obtained for a working population of age 18 to 64 years, at about 4×10^{-4} per rem (4×10^{-2} per Sv). The ICRP made its own estimate of how this fatal cancer risk is distributed among organs and the length of life lost for cancer in each of these organs by further analysis of the data on the atomic bomb survivors.

Based in part on the four fold increase in the average estimates of cancer mortality for low dose and low dose rate radiation exposure, the ICRP recommended a limit on effective dose of 2 rem (20 mSv) per year, averaged over 5 years with the further provision that the effective dose should not exceed 5 rem (50 mSv) in any single year. The ICRP noted that dose limits are needed as part of the control of occupational exposure, both to impose a limit on the choice of dose constraint and to provide a protection against errors of judgment in the application of optimization. The dose limit forms only a part of the system of protection aimed at achieving levels that are ALARA. It represents the point at which regular, extended, deliberate, occupational exposure can reasonably be regarded as only just tolerable.

In 2000, UNSCEAR issued another comprehensive review of the broad field of experimental studies of the radiation effects in cellular systems and in plants and animals. Many of the responses to ionizing radiation observed in plants and animals form a basis for the knowledge of human radiation effects and can often be evaluated in more detail than studies of humans. Furthermore, fundamental radiobiology includes the field of molecular radiobiology which is contributing to an understanding of the mechanisms of radiation response. The UNSCEAR concluded that even at low doses radiation may act as a mutational initiator of tumorigenesis and that anti-tumorigenic defenses are unlikely to show low-dose dependency. Hence, it is unlikely there might be a threshold level of exposure below which biological response does not occur. Such a threshold could only occur if DNA repair processes were totally effective in that dose range or if a single radiation track were unable to produce an effect. The cellular

processes such as apoptosis and cellular differentiation that can protect against later phases of tumorigenesis are judged to be efficient but can be bypassed; there is no reason to believe that those defenses act differently on spontaneous and radiation-induced tumors or have specific dose dependencies.

In their 2000 report, UNSCEAR derived risk estimates for radiation-induced cancer. For a global population of all ages and both genders, it is suggested that the lifetime risk estimate for solid cancer mortality might be taken as 9×10^{-4} per rem (9×10^{-2} per Sv) for men and 13×10^{-4} per rem (13×10^{-2} per Sv) for women. The uncertainties in the estimates may be a factor of 2, higher or lower. The estimates could be reduced by 50 percent for chronic exposures and solid cancer incident risks can be taken as being roughly twice those for cancer mortality. Lifetime cancer risk estimates for those exposed as children might be twice the estimates for a population exposed at all ages. Finally, UNSCEAR reiterated that the experience of the Japanese atomic bomb survivors provides compelling evidence for linearity in estimating excess risks of solid cancers; therefore, as a first approximation, linear extrapolation of the estimates of cancer risk at 100 rem (1 Sv) could be used for estimating solid cancer risks at lower doses.

In contrast to the recommendations of the ICRP and the technical reviews by UNSCEAR and the BEIR committee, the French National Academy of Medicine and the French Academy of Sciences published a report in March 2005 that cautioned against using the linear, no threshold (LNT) hypothesis to estimate radiation risk at very low radiation exposures. The French report suggested that there is a lower effectiveness of inducing biological damage from low doses (compared to acute exposures of high dose radiation), or the existence of a practical threshold. The report suggested that the lower effectiveness could be related to either the failure of a very low dose to sufficiently activate cellular signaling for DNA repair mechanisms, or to an association between apoptosis, error-free DNA damage repair, and increased immune surveillance. However, the French did acknowledge that they did not find it possible to define the threshold level (between 0.5 and 5 rem (5 and 50 mSv)) or to provide the evidence for it.

This French report raises doubts on the validity of using the LNT hypothesis for evaluating the carcinogenic risk of low dose (< 10 rem; 100 mSv) radiation exposure and even more for very low dose (< 1 rem; 10 mSv) exposures. While acknowledging that the LNT concept can be a useful, pragmatic tool for instituting and managing a system of radiological protection, the report asserts that LNT is not based on current biological concepts, so it should not be used for assessing the risks associated with low and or very low doses.

The 2006 report of the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation (BEIR-VII) is their most recent reevaluation of the health risks of radiation exposure based on a review of all relevant biological information important to the understanding of modeling of those health effects. The BEIR committee considered radiation risk information from studies of persons exposed for medical, occupational, and environmental reasons. Along with the review of these bodies of information, the committee reviewed data on cancer mortality and incidence from the survivors of the Hiroshima-Nagasaki atomic bombings based on

improved dose estimates that were published in 2002. Other phenomena reviewed by the committee that suggests enhancement or reduction in radiation effects include adaptive response, low-dose hypersensitivity, bystander effect, hormesis, and genetic instability; biological effects based on phenomenological data with little mechanistic information. The committee concluded that the current scientific evidence is consistent with a hypothesis that there is a linear dose-relationship between exposure to ionizing radiation and the development of radiation-induced solid cancers in humans. The committee further judged that it is unlikely that a threshold exists for the induction of cancers but notes that the occurrence of radiation induced cancers at low doses will be small. Results based on linear models and reduced by a dose and dose rate effectiveness factor of 1.5 (versus 2) for the U.S. population varies from 4.1 to 6.1 x 10^{-4} per rem (4.1 to 6.1 x 10^{-2} per Sv) for fatal solid cancer. Results for leukemia are based on a linear-quadratic model.

Other health effects such as heart disease and stroke occur at high radiation doses, but the report concluded that additional data must be gathered before an assessment can be made of any possible connection between low doses of radiation and noncancer health effects.

The biological risks of radiation exposure that were documented by UNSCEAR in their 2006 report note that risk estimates vary for different populations (e.g., U.S. vs Japanese) and with different risk models. The 2006 UNSCEAR risk estimates are somewhat lower, although not much lower, than those previously estimated by UNSCEAR (2000) or the U.S. National Academy of Science (BEIR – V, BEIR – VII). A reduction of about 10 percent in the solid cancer risk estimate may be due to the new atomic bombings dosimetry that was revised in 2002 and another small 3 – 7 percent reduction may be due to increased follow-up of the atomic bomb survivors. The statistical uncertainties in the above estimates may be on the order of a factor of 2 higher and the lower bound includes zero. The UNSCEAR also noted that lifetime solid cancer risk estimates for those exposed as children might be factors of 2-3 times higher than the estimates for members of the public; studies of *in utero* radiation exposures show that the fetus is particularly sensitive with elevated risk being detected at doses of 1 rad (10 mGy) and above. Finally, UNSCEAR concluded that the experience of studies of the survivors of the atomic bombings is consistent with a linear dose response for the risk of all solid cancers combined. Therefore, as a first approximation, linear extrapolation of the estimates of risk following an acute dose of 100 rem (1 Sv) can be used for estimating solid cancer risks at lower doses.

The ICRP issued new recommendations on radiological protection in 2007, which formally replaced the 1990 recommendations. The revised recommendations included consideration of the detriment arising from cancer, non-cancer, and heritable effects of radiation on health. The accumulation of cellular and animal data relevant to radiation protection since 1990 has strengthened the view that DNA damage response processes in single cells are critically important to the development of cancer after radiation exposure. For the purposes of radiation protection the ICRP continues to judge that the weight of evidence on fundamental cellular processes coupled with dose-response data supports the view that in the low dose range, below 10 rem (100 mSv), it is scientifically plausible to assume that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organ or tissue.

The ICRP also continues to emphasize that while the LNT model remains a scientifically plausible element in its system of radiological protection, biological/epidemiological information that would unambiguously verify the hypothesis that underpins the model is unlikely to be forthcoming. In arriving at this judgment, the ICRP considered potential challenges associated with information on cellular adaptive responses, the relative abundance of spontaneously arising and low-dose-induced DNA damage and the existence of post-irradiation cellular phenomena of induced genetic instability and bystander signaling. Since the estimation of cancer risk incidence and mortality is based upon direct human epidemiological data, any contribution from these biological mechanisms would be included in that estimate.

Since 1990, further epidemiological information from medical, occupational, and environmental exposures has accumulated. Much of the new information reviewed by ICRP came from additional follow-up of survivors from the Hiroshima-Nagasaki atomic bombings. Overall, the 2007 ICRP recommendations reported that the current cancer risk estimates derived from the survivors of the atomic bombings are not greatly changed but the inclusion of cancer incidence data provides a firmer foundation for cancer risk modeling.

A follow-up assessment conducted by UNSCEAR in 2010 reconfirmed many of UNSCEAR's 2006 risk estimates derived from the atomic bomb survivors. By contrast, many other groups were exposed over long periods to low doses, and sometimes the exposure was from internally incorporated radionuclides. Valuable information has been provided by epidemiological studies of the health of workers at the Mayak nuclear complex in the southern Urals of the Russian Federation, and of the population near the Techa River whose exposure was due to radioactive discharges from that facility. Follow-up of those exposed as a consequence of the Chernobyl accident has provided useful information of the effects of low-dose external radiation exposure, and on the effects of thyroid exposure to radioiodine. Overall, the cancer risk estimates from these studies do not differ significantly from those obtained from the studies of the atomic bombing survivors in Japan. By contrast, studies on human populations living in areas with elevated natural background radiation in China and India do not indicate that radiation at such levels increases the risk of cancer.

In 2011, the ICRP issued a statement concerning recent epidemiological evidence which suggests that there are some tissue reaction effects (e.g., heart disease, stroke, and cataracts); where threshold doses might be significantly lower than previously considered. The threshold in absorbed dose for these tissue reaction effects is now considered to be 50 rad (0.5 Gy). As a result, the ICRP recommended that the occupational equivalent dose limit to the lens of the eye be reduced from 15 rem (150 mSv) in a year to 2 rem (20 mSv) in a year, averaged over defined periods of 5 years, with no single year exceeding 5 rem (50 mSv).

In April 2011, the U.S. Environmental Protection Agency (EPA) published a revision of their methodology and estimates for radiogenic cancer risk for the U.S. population (EPA 402-R-11-001). This revision was based upon the estimates and methodology from the BEIR VII report, with additional extensions and modifications for the risk from low LET radiation, estimates for additional types of cancer, and modifications for estimating breast cancer mortality risk and thyroid cancer risk. Summary risk coefficients were calculated for a stationary population defined by the 2000 U.S. vital statistics. For uniform whole-body exposure of low-dose gamma radiation to the entire population, the cancer incidence risk coefficient is 1.16×10^{-3} per rad (1.16×10^{-1} per Gy) with a 90% confidence interval of 5.6×10^{-4} to 2.1×10^{-3} per rad (5.6×10^{-2} to 2.1×10^{-1} per gy). The corresponding coefficient for cancer mortality is about one-half that for

incidence: 5.8×10^{-4} per rad (5.8×10^{-2} per Gy). The EPA plans to use this information to develop a revision of Federal Guidance Report 13, "Cancer Risk Coefficients for Environmental Exposure to Radionuclides."

Conclusions:

The NRC staff has concluded that there have been significant changes in radiation risk estimates, and the methodologies for recommending dose limits. These changes have been developed by both national and international organizations. Given these changes, the staff has concluded that there is a sufficient risk informed scientific basis to move the NRC's regulatory framework to a greater degree of alignment with the ICRP recommendations.

Summary of Stakeholder Interactions

Background:

In the Staff Requirements Memorandum (SRM) for SECY-08-0197, dated April 2, 2009, the Commission approved the staff recommendation to begin engagement with stakeholders and interested parties to initiate development of the regulatory basis (previously referred to as technical basis) for possible revision of the Nuclear Regulatory Commission's (NRC's) radiation protection regulations, as appropriate and where scientifically justified, to achieve greater alignment with the 2007 International Commission on Radiological Protection (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 the staff where changes to the NRC's regulations may be merited; 2) will help establish a regulatory basis for instances where exceptions to ICRP Publication 103 continue to be appropriate; and, 3) will result in continued high assurance that our regulatory framework for radiation protection is sound.

In response to this SRM-SECY-08-0197, the NRC staff has engaged a wide range of stakeholders on a set of significant technical issues related to increasing alignment with international recommendations, standards and the radiation protection framework. The set of issues was guided by the staff presentation in SECY-08-0197. The issue topics discussed included use of new methodology and terminology, occupational total effective dose, the occupational dose limit for the embryo/fetus of a declared pregnant female, and As Low As Reasonably Achievable (ALARA) planning. The issue of limits for the lens of the eye was added following the publication of the statement by the ICRP in April 2011. Additional topics were raised during the discussions, including use of the International System of units and reporting requirements for occupational exposure.

Three *Federal Register* Notices 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 discussion have taken place with a variety of professional societies, licensee organizations, public interest groups, and the States. A total of 59 comments were received from these formal requests, and are publicly available. In the fall of 2010, a series of facilitated round table workshops were held in Washington, D.C., Los Angeles, California, and Houston, Texas.

This summary is divided into three sections:

I. Professional Societies and Organizational Meetings
II. Advisory Committees
III. Facilitated Round Table Workshops

Enclosure 3 provides the summary of stakeholder views for each of the technical issues.

I. Professional Societies and Organizational Meetings

The NRC staff has actively engaged various organizations and professional societies to discuss the issues and options. The following list of 24 meetings illustrates the wide range of stakeholder types that have had discussions with the staff.

June, 2009, 28th International Dosimetry and Records User's Symposium, San Diego, CA. Radiation protection and dosimetry representatives from a variety of licensee types, specifically including nuclear power.

June, 2009, 56th Annual Meeting of Society of Nuclear Medicine, Toronto, Canada. Medical professionals, particularly those involved in nuclear medicine.

June, 2009, Fuel Cycle Information Exchange, Bethesda, MD. Licensee representatives of fuel facilities licensees.

July, 2009, 54th Annual Health Physics Society Meeting, Minneapolis, MN. Radiation protection representatives from a wide variety of licensee types, national laboratories, and international organizations.

August, 2009, The 2009 National State Liaison Officers Conference (SLO), Rockville, MD. Governor-appointed SLOs.

October, 2009, American Society of Nuclear Cardiology, Minneapolis, MN. Medical professionals in the area of nuclear cardiology.

November, 2009, National Aeronautics and Space Administration (NASA) Health Physics Group, Teleconference. Radiation protection staff from NASA program centers.

January, 2010, 2010 Information System on Occupational Exposure (ISOE) North American ALARA Symposium/EPRI Radiation Protection Conference, Ft. Lauderdale, FL. Representatives of national and international power reactor organizations.

February, 2010, Institute for Energy and Environmental Research, Silver Spring, MD. Representatives of environmental non-government organizations.

March, 2010, Regulatory Information Conference, North Bethesda, MD. Representatives from a variety of licensee types and national and international organizations.

April, 2010, Conference of Radiation Control Program Directors, Newport, RI. Representatives of state radiation control programs, including both Agreement and non-Agreement States.

June, 2010, Fuel Cycle Information Exchange, Bethesda, MD. Licensee representatives of fuel facilities licensees.

July, 2010, American Association of Physicists in Medicine, Philadelphia, PA. Medical professionals, particularly those involved in nuclear medicine.

July, 2010, Nuclear Energy Institute (NEI) Health Physics Forum, Clearwater Beach, FL. Radiation protection representatives from domestic and some international nuclear power facilities.

September, 2010, 2010 Texas Radiation Regulatory Conference, Austin, TX. Representatives from a variety of industrial and medical licensees in the State of Texas.

January, 2011, ISOE ALARA Conference, Ft. Lauderdale, FL. Representatives of national and international power reactor organizations.

March, 2011, Regulatory Information Conference, North Bethesda, MD. Representatives from a variety of licensee types and national and international organizations.

April, 2011, 2011 Triennial NASA Health Physics Training Meeting, Washington, D.C. Radiation protection representatives for each of NASA's laboratories and centers.

June, 2011, 56th Health Physics Society Annual Meeting, West Palm Beach, FL. Radiation protection representatives from a wide variety of licensee types, national laboratories, and international organizations.

August, 2011, NEI Radiation Protection Forum, Seattle, WA. Radiation protection representatives from domestic and some international nuclear power facilities.

September, 2011, Child Health Corporation of America Radiology Directors Forum, Dallas, TX. Representatives from radiology programs in children's hospitals.

October, 2011, 2011 ICRP International Symposium, North Bethesda, MD. Representatives of national and international organizations.

January, 2012, ISOE International ALARA Conference, Ft. Lauderdale, FL. Representatives of national and international power reactor organizations.

March, 2012, Regulatory Information Conference, North Bethesda, MD. Representatives from a variety of licensee types and national and international organizations.

II. Advisory Committees (ACRS and ACMUI)

November 6, 2008, Advisory Committee on Reactor Safeguards. Rockville, MD

February 6, 2009, Advisory Committee on Reactor Safeguards, Rockville MD

May 7-8, 2009, Advisory Committee on the Medical Use of Isotopes, Rockville, MD

December 16, 2009, Advisory Committee on Reactor Safeguards, Rockville, MD

April 27, 2012, Advisory Committee on Reactor Safeguards, Rockville, MD (Scheduled)

III. Facilitated Round Table Workshops

Each of the facilitated round table workshops 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 *Federal Register* Notices, are publicly available.

Washington DC/Silver Spring:

October 25, 2010 - October 27, 2010. Changes to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 discussed on October 25th and 26th. Changes to 10 CFR Part 50 Appendix I discussed on October 27th.

Participant Organizations/Agencies:

- Exelon Nuclear
- U. S. Department of Energy
- Organization of Agreement States, Inc (OAS)
- United States Enrichment Facility (Paducah, KY)
- Canadian Nuclear Safety Commission
- Troxler Electronic Laboratories
- Environmental Protection Agency
- National Institute of Health (NIH)
- QSA Global / International Source Suppliers and Producers Association
- Oak Ridge National Laboratory/Battelle
- Conference of Radiation Control Program Directors (CRCPD)
- Kettering Medical Center (OH)
- Duke Energy
- American College of Radiology
- Johns Hopkins Hospital
- Energy Solutions
- NEI
- American Portable Nuclear Gauge Association
- Southern Nuclear Company
- Dominion Resources
- Society of Nuclear Medicine
- Triad Isotopes, Inc.
- S.M. Stoller Corporation

Los Angeles, California:

November 3, 2010- November 4, 2010

Participant Organizations/Agencies:

- NEI
- University of California Los Angeles Medical Center
- AREVA
- Valley Industrial X-Ray and Inspection Services
- Southern California Edison
- University of California Los Angeles
- American Association of Physicists in Medicine
- Children's Hospital Los Angeles
- CRCPD
- California Department of Public Health
- University of Southern California Medical Center
- Los Angeles County Department of Public Health
- Hoag Memorial Hospital Presbyterian
- Therapy Physics, Inc.
- American College of Radiology
- Perkin Elmer / Council on Radionuclides and Radiopharmaceuticals
- City of Hope Medical Center
- Veterans Affairs Medical Center

Houston, Texas:

November 8, 2010 - November 9, 2010.

Participant Organizations/Agencies:

- Acuren Inspection (Houston)
- Baker Hughes (Lafayette, Louisiana)
- Baylor College of Medicine (Houston, Texas)
- Energy Solutions (Salt Lake City)
- Lamco and Associates
- H&H X-Ray Services
- NEI
- Radiation Technology, Inc. (Austin)
- Metco
- Louisiana State University
- OAS / Louisiana Department of Environmental Quality
- CRCPD / Texas Department of State health Services
- M.D. Anderson Cancer Center (Houston, Texas)
- South Texas Project Operating Company
- Stark Test (Houston, Texas)
- TC Inspection
- International Isotopes
- Society of Nuclear Medicine

Assessment of Technical Issues and Feedback

Background:

In response to the Staff Requirements Memorandum (SRM) for SECY-08-0197, the staff has engaged stakeholders on a set of technical issues related to increasing alignment with international recommendations and standards. The set of issues was guided by the staff presentation in SECY-08-0197, and evolved somewhat during the stakeholder dialogue process. The issue topics discussed included use of a new methodology and terminology, occupational total effective dose, the occupational dose limit for the embryo/fetus of a declared pregnant female, and As Low As Reasonably Achievable (ALARA) planning. The issue of limits for the lens of the eye was added following the publication of the statement by the International Commission on Radiological Protection (ICRP) in April 2011. Additional topics were raised during the discussions, including use of the International System of units (SI) and reporting requirements for occupational exposure.

In the sections which follow, each issue area is presented, including a summary of the staff proposed position, the options initially proposed for discussion, the feedback and comments received from stakeholders, and the staff's conclusion on the direction to pursue for further development of the regulatory basis (previously referred to as technical basis) for a proposed rule.

Outline:

1) Methodology and Terminology

Summary of Staff Recommendation:

- Change radiation and tissue weighting factors to ICRP Publication 103.
- Adopt current metabolic (inhalation & ingestion) models.
- Revise Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 Appendix B Annual Limits on Intake (ALI), Derived Air Concentrations (DAC), Effluent Concentrations, and Release to Sewer values based on new ICRP 103 dose coefficients when available.
- Adopt Total Effective Dose (TED) in place of Total Effective Dose Equivalent (TEDE), with flexibility in implementation period.
- Incorporate updates of methodology and terminology in revision of 10 CFR Part 50, Appendix I, and in other NRC CFR parts as revision opportunities become available.
- Consider best mechanisms for implementation to facilitate transition and minimize impacts.

Options Presented for Stakeholder Discussion:

- No Change – Use existing methodology and terminology.
- Update to ICRP 103 methodology and terminology.
- Allow use of either current or new terminology for effective dose.

Supporting Information:

The ICRP recommendations are supported by a series of documents that reflect scientific information on the intake, distribution, retention, and elimination of radioactive material from the body, and the calculation of dose in various organs and tissues. With each revision of the recommendations, there have been corresponding revisions to tissue weighting factors, radiation weighting factors, and the dose coefficients calculated for the intake and retention of radionuclides in the body.

The materials supporting the 1977 ICRP recommendations are contained in ICRP Publication 30. Supporting the 1990 ICRP recommendations, updated information was published in ICRP Publication 56 “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1, ” Publication 61, “Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations”, Publication 67, “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients, ” Publication 68, “Dose Coefficients for Intakes of Radionuclides by Workers, ” Publication 69 “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 3 Ingestion Dose Coefficients, ” Publication 71, “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients, ” Publication 72, “Age-dependent Doses to the Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients, ” and Publication 74, “Conversion Coefficients for use in Radiological Protection against External Radiation.”

The ICRP is still in the process of preparing the updated dose conversion factors that are used to calculate doses from intakes of radioactive material and reflect the changes in Publication 103. These new dose coefficients will be compatible with the new tissue weighting factors, radiation weighting factors, updated nuclear decay data, and the updates of metabolic models.

The first report, for external exposure, is expected to be published in the next year. The calculations for Occupational Intake of Radionuclides will be published in a set of 5 publications, culminating in a completely revised set expected by the end of 2015. Dose conversion factors for members of the public are also under development, with publication expected in 2014.

10 CFR Part 20 uses the term TEDE to represent the summation of dose received from sources external to the body and the dose from the intake of radioactive materials. The term was actually created by the NRC staff for the NRC's 10 CFR Part 20 regulations, because at that time the ICRP used an entire phrase (the sum of the dose equivalent from sources external to the body, and the committed effective dose equivalent for the intake of radionuclides) to describe the summation of internal and external exposure. With the 1990 ICRP recommendations, there were some changes in the way that tissue and radiation quality factors were defined and used (moving from quality factors to radiation weighting factors), and there was a corresponding change in the terminology used, to Effective Dose (ED) or TED when additional emphasis was being added to make clear that the reference was to the summation of the contributions from external exposure, and from the intake of radioactive material. These terms are used in various ICRP publications.

10 CFR Part 20 defines the tissue weighting factors in the § 20.1003 definition of weighting factor W_T. The quality factors and absorbed dose equivalencies for different types of radiation are found in § 20.1004. An update to reflect the tissue weighting factors and radiation weighting factors from ICRP Publication 103 would amend these sections.

10 CFR Part 20, Appendix B, contains ALI and DAC values for occupational and public exposure via airborne or liquid pathways. These ALI values are generated using the tissue weighting factors, radiation quality factors, and radionuclide specific information to calculate a generic quantity of a radionuclide that would result in a dose of 5 rem (50 mSv) to a reference individual. The DAC values are similarly calculated to represent the concentration of material, in air, which, if breathed continuously for 2000 hours, would result in the intake of 1 ALI. These values are used by licensees as one acceptable method for demonstrating compliance with the dose limits of 10 CFR Part 20. These values have also been used in other portions of the regulations as trigger values for certain actions, such as reporting. If the methodologies are modified, NRC staff will need to review related NRC regulations, outside of 10 CFR Part 20, to determine the impact. The values in 10 CFR Part 20, Appendix B, would need to be amended to reflect the new tissue and radiation weighting factors.

A consistent use of updated tissue and radiation weighting factors will result in some changes to the calculated values of ALI and DAC. In some cases the ALI values will increase, indicating that a larger quantity of material corresponds to the dose limit. In other cases, the ALI values will decrease. Until all of the calculations have been completed, it is not possible to give complete details of the changes. The staff understands that the changes between the calculated values for the 1990 ICRP recommendations and the 2007 ICRP recommendations are not expected to be large. However, there are some more substantial differences between the 1977 ICRP recommendations, and the 2007 recommendations. One such change is ALI and DAC values for Uranium and Thorium, which will increase because the dose per unit intake of radionuclide is smaller than estimated in 1977. Because this change was present in the values calculated for the 1990 ICRP recommendations, many of the licensees impacted by this change have already requested amendments to their license to allow use of the newer information.

Stakeholder Views:

The discussion of methodology is the one area in which most of the stakeholders agreed that change was warranted. Many stakeholders expressed their general support for changes to reflect the more up-to-date modeling, and suggested that it was important to have the regulatory framework use the best available information. Furthermore, stakeholders suggested that the NRC wait for all the information to be available, and make the change all at once, rather than undertake a piecemeal approach, or some interim change, so that licensees would not have to make two or more sets of changes to their procedures and programs in a relatively short period of time.

While there was general support for changes, there were also some concerns expressed about using the newer factors and methodology. For example, the staff has had limited success in engaging some of the other public and environmental Non-governmental Organizations (NGO) stakeholders, in part because the discussions have focused on occupational exposure, rather than public or environmental exposure. These groups have, in other forums, raised concerns about the use of the effective dose concept and the use of the latest values if the use of these values would result in an increase in any of the calculated ALI or DAC values. Such changes are seen by these stakeholders as decreasing safety, irrespective of the fact that the underlying dose criteria remained unchanged.

The issue of changing terminology generated a mixed response, with many stakeholders agreeing that the terminology should be consistent with that used internationally and in the scientific literature. Stakeholders also recognized that the change in terminology, corresponding to a change in the methods for calculations, would be a logical and consistent move, and support a clear differentiation of when requirements were changed.

Stakeholders also identified some concerns with changing the terminology to that used in the 2007 ICRP recommendations. Stakeholders identified several issues, including the cost benefit associated with the changes. They noted that the change in terminology to TED from TEDE is not a significant change in the regulatory approach. Nevertheless, the training costs associated with the change could be significant, as well as difficult to explain. Furthermore, stakeholders noted that the necessary changes to computer programs and algorithms could be substantial, and urged the NRC to make sure that the changes are worth those costs.

Staff Analysis and Conclusions:

The starting point of the analysis is the present regulatory basis within the NRC regulatory framework. 10 CFR Part 20 is based upon the models and weighting factors available in the late 1970's. Other portions of the regulations, and in particular 10 CFR Part 50, Appendix I, are still based on the models and approach from the 1950's. Furthermore, there are some licensees who have been authorized to use the models and weighting factors from the 1990's by NRC approvals of licensee requests.

Relying upon a regulatory framework that relies upon scientific information from different dates raises issues. In particular, the oldest methodology from the 1950's does not readily lend itself to summation exposures from intakes of radioactive material with exposure received from sources external to the body. For the methodology from the 1970's, it is possible to sum

internal and external exposures. In each case, the changes in methodology and knowledge allow for a more accurate prediction of dose from an intake of radioactive material.

Changes to the modeling and weighting factors allow for a consistent, up-to-date assessment of exposures. For example, the August 1, 2007, letter from the Advisory Committee on Nuclear Waste and Materials to Chairman Klein, ACNWS-0266 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML072120415), recommended that certain standard review plans in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," be updated, including computer codes, methodologies, and parameter values cited in referenced regulatory guides, supporting NUREGs, and other documents. The August 1, 2007, letter describes a three step approach suggested by health physics staff in the Office of New Reactors (NRO) to address the weaknesses in NRC's dose methodologies and update them. The NRO staff suggested that the first step could update critical parameters such as dose conversion factors. The second step could then be the update of other important parameters such as shielding and biological accumulation factors. Finally, the third step could systematically review all dose methodologies used and comprehensively update all of them to ensure that a risk-informed approach is employed.

In the 1990 ICRP recommendations, the terminology was also changed from Effective Dose Equivalent to ED. This change was made to reflect the move from the quality factor approach to radiation effects weighting to the use of radiation weighting factors. While the staff recognizes the preference, from a regulatory stability standpoint, for retaining TEDE, the staff believes it is appropriate to change the terms to match the corresponding change in methodology and numerical values. From the standpoint of a retrospective review of records, a change in the terminology at the time of a change in methodology would facilitate identification of the approach used in generating the record.

The staff recognizes the concerns of some stakeholders that an amendment of the regulation would result in both increases and decreases in ALI values for compliance with the dose limit. A consistent implementation of the new methodology and weighting factors will result in some ALI values increasing, and others decreasing, based on our updated scientific basis. The staff believes that the changes should be made consistently, both up and down, so that the values represent a coherent set with the same scientific support.

The staff will also need to engage stakeholders on the dose which the ALI represents. Under the recommended set of options, the dose limit would be reduced to 2 rem (20 mSv). The revised ALI and DAC values would thus also have to be adjusted to correspond to the new dose limits. As part of this process, an examination will be needed on the impact of these changes to other portions of the NRC's regulations where ALI and DAC values are used as triggers for a regulatory action such as reporting. The staff will need to carefully examine all cross reference and uses of ALI and DAC values in regulations and guidance to develop a complete analysis of impacts.

The primary benefit in revising 10 CFR Part 20 to incorporate the recommendations and standards of ICRP 103 is that the demonstration of compliance would be based on the current scientific information. It is also important to ensure that the methodology and factors being used are a consistent set. For example, when the NRC approved licensee requests to use the methodology associated with the 1990 ICRP recommendations, one of the license conditions

was that the same methodology be used for the entire radiation protection program. This requirement was to avoid a possible situation in which results from different systems were "cherry picked" as advantageous for one reason or another.

The benefit of consistently moving to the updated methodology across the entire NRC radiation protection regulatory framework is greater than that seen for 10 CFR Part 20 alone. As noted previously, 10 CFR Part 50, Appendix I relies upon methodologies dating back to the 1950's. As a result, power reactor licensees must use entirely different approaches to demonstrating compliance with different portions of the regulations, which is both time consuming and difficult to explain. In that regard, a move to a consistent methodology should lead to an increase in public confidence and transparency.

The staff recognizes that the benefits of updated methodologies are not easily quantified. It is possible, however, to have quantitative measures of costs. There will, in fact, be substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology.

These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by the NRC regulations, and the value of terminology that represents the updated science which is used by many other nations.

It is possible that the staff will conclude that, despite the flexibility afforded by the Commission in attempting to demonstrate a "substantial increase in protection," that a positive demonstration of benefit cannot be made. The Commission's 1993 SRM also indicated that the staff could request that the Commission make an "exception" to the Backfit Rule. This type of request is discussed further in Section 10 with respect to "administrative exemption."

As the process moves forward, the staff will need to engage stakeholders to develop quantitative estimates of impacts, and examine areas in which flexibility in implementation can offset or mitigate those impacts. For example, it may be possible to allow a much longer transition period for the terminology to be implemented in training and documents.

The staff recommends that the regulatory framework be updated to reflect the new terminology and dose calculation methodologies, so as to align with the current scientific approach to estimating radiation exposure and risk. Further, the staff recommends that a rulemaking not be initiated to reflect these changes until all of the dose coefficients and other supporting information are available, so that a single, comprehensive, change can be made to the relevant paragraphs and appendices of 10 CFR Part 20. Changes to other portions of the NRC's regulations also need to be made to reflect the updated methodology and terminology. In particular, the staff recommends that this approach also be taken in a revision of 10 CFR Part 50, Appendix I.

Note that this recommendation relates only to the terms used to refer to dosimetry. The staff is not proposing that we adopt many of the words used internationally to describe the principles of radiation protection. For example, as described later in this package, the staff is recommending against the use of the term "constraint." This will be further described in Section 5 on ALARA planning.

The staff believes that this recommendation is consistent with Commission direction to consider revision of the safety criteria in 10 CFR Part 32 as part of its effort to develop the regulatory basis for possible revision of the NRC's radiation protection regulations, and Commission direction to provide an expanded proposed rule for 10 CFR Part 61 to consider the pros and cons of allowing licensees the flexibility to use ICRP dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste (SRM-SECY-11-0129, SRM-COMWDM-11-002/COMGEA-11-002).

2) Limits for Occupational Total Effective Dose Equivalent

Summary of Staff Recommended Position:

- Change occupational dose limit to 2 rem (20 mSv).
- Develop provision to allow a licensee to apply for use of a dose limit up to 5 rem (50 mSv) in any one year, and 10 rem (100 mSv) over 5 years, upon application and approval.

Options Presented for Stakeholder Discussion:

1. No change.
2. ICRP max and average recommendation.
3. Single limit at 2 rem (20 mSv).

Supporting Information:

The area of greatest discussion, and controversy, is the area of possible changes to the mechanisms for controlling occupational exposure. This issue includes the occupational dose limits and the requirement to reduce exposures consistent with the ALARA principle. The discussion on ALARA is found in Enclosure 3, Section 5. There is a perception on the part of the international community, and some stakeholders, that alignment or lack thereof of the NRC regulations with the ICRP recommendations can be measured by whether the occupational dose limit is changed.

The current 10 CFR Part 20 occupational TEDE limit is 5 rem per year (50 mSv). The international recommendations have, since 1990, incorporated a lower limit of 10 rem (100 mSv) over a 5 year period, with a maximum of 5 rem (50 mSv) in any one year. International standards, such as those of the International Atomic Energy Agency (IAEA), have adopted these limits. The United States is now an outlier, because some variation of these limits is in place in most other nations. The trend internationally is to further simplify the limit to a single value of 2 rem (20 mSv), as evidenced in the draft Euratom Basic Safety Standards Directive in the European Union.

The selection of a recommended dose limit by ICRP in 1977 was based on a comparison of the radiation risk of fatal cancer with the average annual risk of accidental death in industries generally accepted as having a safe working environment. According to ICRP, such industries, at that time, could be defined as exhibiting an annual mortality risk of approximately one person in 10,000 from industrial accidents. The recommended limit was suggested to provide radiation workers with at least that level of protection. The selection of a 5 rem (50 mSv) value was based on an expectation that most individuals protected by such a limit would be unlikely to

exceed 1 rem (10 mSv) in a year. It was actually the radiation risk of 1 rem that corresponds numerically with the average annual accidental death rate in safe industries.

In 1990 ICRP reduced the recommended occupational dose limit in response to the changes in estimated radiation risk (see Enclosure 1). The recommended limit was expressed as an average and a maximum value in order to provide flexibility for possible implementation issues, while achieving an objective to restrict the cumulative occupational exposure to less than 100 rem (1 Sv). The 100 rem (1 Sv) level was selected from a range of possible options as a risk informed judgment that an aggregated risk of 5 percent from fatal cancer, serious nonfatal cancer, estimate of length of life lost from fatal cancer, and serious hereditary effects would be unacceptable. The ICRP also noted that the value was selected with the assumption that, with the application of sound radiation protection practices the limit would only rarely be approached.

In the United States, the majority of occupationally exposed individuals receive less than 2 rem (20 mSv) per year. However, a small percentage of individuals receive larger exposures, up to, and occasionally above the current limit of 5 rem (50 mSv). While the nuclear power community has been very successful in reducing individual exposures, such that only a very limited number of individuals exceed 2 rem (20 mSv) in a year, other segments of the regulated community, such as industrial radiography and various medically related activities have somewhat greater percentages of individuals above the levels recommended internationally. Stakeholder interactions lead the staff to believe that some of these individuals may be receiving doses close to the 5 rem (50 mSv) limit over multiple years, and thus there is the possibility that they may exceed the cumulative levels of exposure considered appropriate. Detailed information on these cumulative exposures is difficult to ascertain because some segments of the regulated community are not required to report occupational exposure.

The numerical value of the dose limit is also linked to other provisions of the regulations, including the basis for calculations for ALI values to demonstrate compliance with the limits (see Enclosure 3, Section 1), criteria for monitoring, and event reporting. If a change to the occupational dose limit is made, NRC staff will need to review the NRC regulations outside of 10 CFR Part 20 to determine if the basis for those requirements are either sufficiently independent of the occupational dose limit to remain unchanged or whether an adjustment should be made to conform with the regulations.

Stakeholder Views:

The issue of changes to occupational dose limits has been the single greatest point of concern and discussion in our interactions with stakeholders.

Almost all stakeholders objected to any change, saying it was not necessary, would impact the conduct of work and the delivery of medical care, could potentially impact compensation and legal claims, and was not scientifically supported. Some public stakeholder groups, however, supported a reduced occupational limit. A sampling of some of the salient points follows.

A change to the dose limits was adamantly opposed by most licensee groups. Medical licensees, for example, stated that a reduction in the occupational limit would result in an adverse impact to health care, both in the treatment of patients, and in the training of physicians and other medical professionals. As part of the discussions, these stakeholders indicated that the delivery of health care in the United States is different from other countries, in that there is a

greater use of radiation and radioactive materials in diagnosis and treatment of patients. Some medical licensees stated that reducing the occupational limit would result in an increase in non-compliance because medical professionals would remove their dosimetry badges when they approached the annual occupational limit. During the workshops there were a number of references to actions which would, in the opinion of the staff present, constitute non-compliance with the current regulations, although no specific allegations were made. It should be noted that changes (or not) to limits is not the solution of these potential non-compliance issues. This is an area which would have to be addressed by inspection and enforcement, irrespective of the final regulations adopted.

Stakeholders representing the medical community also mentioned the need for standards that are based on solid scientific evidence, instead of reducing the occupational limit without having the appropriate scientific basis to support that reduction. According to these comments, there are very limited opportunities for them to increase the cost of doing business without specific and very clear benefit both to those who are doing the work, as well as to the patients who are receiving those studies. Thus a change in the dose limit was viewed as an economic penalty on the providers of health care. Essentially, they indicated that a change in the occupational dose limit would have an impact on the practice of medicine, as the increased costs would force some medical practioners to abandon nuclear medicine, and there would then not be enough doctors available to perform the needed procedures.

One area of considerable discussion with the States, and with stakeholders in the medical area, was the use of effective dose for demonstrating compliance for external exposure. The Commission amended the definitions in 10 CFR 20.1003 and 10 CFR 50.2 (72 FR 68043; December 4, 2007), to clarify the definition of TEDE to mean the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition of TEDE allows a licensee to substitute “effective dose equivalent” for “deep dose equivalent” for external exposures. The December 4, 2007, rulemaking also made a conforming change to 10 CFR 20.1201(c) to clarify the determination of occupational radiation dose for adults. This rulemaking became effective on February 15, 2008 (72 FR 72233, December 20, 2007). The provision, or some variation thereof, has been adopted by many, but not all states. Medical stakeholders, particularly those involved in interventional radiology and cardiology, noted that a consistent recognition of effective dose, rather than a requirement to use the deep dose equivalent at the point of highest exposure, would greatly facilitate their ability to comply with the dose limits. In fact, one stakeholder noted that if a realistic estimate of effective dose was allowed, there would not be an issue with these medical fields complying with a dose limit of 2 rem (20 mSv).

Stakeholders representing industrial radiography, oil well logging, and gauging, including the International Source Suppliers and Producers Association, stated that their activities require that a higher occupational dose be received during the performance of those activities. To meet a lower limit, additional trained individuals would be needed to complete any particular job. In addition, some of these stakeholders stated that the higher activity of sources typically used by industrial radiographers and similar professions in the United States would make it difficult to operate within an annual occupational limit less than 5 rem (50 mSv). The staff is still seeking to understand how these ICRP recommendations have been implemented in other countries where the limit was reduced a number of years ago in response to the ICRP Publication 60 recommendations (see Enclosure 4).

The staff notes that the suggestion by stakeholders that the selection of an occupational dose limit should be related to the activities performed, and the size of the sources employed, is problematic. The staff asserts that the setting of a proper health and safety framework to provide adequate protection must be independent of the size of the sources that may be used. The recommendations of the ICRP and National Council on Radiation Protection and Measurements (NCRP), and the current NRC regulations, apply to all types of occupational exposures, and are intended to provide a consistent, adequate level of protection. The staff does not believe that the size of a source, or the various uses of radioactive materials, is a credible or appropriate argument to be made for changing, or not changing, the occupational dose limits.

Some stakeholders stated that changing the dose limits might open an opportunity for law suits because it might have the implication of saying we have been working unsafely all these years. Some stakeholders, such as portable gauge users, did not view the possible change in the occupational dose limit as having an impact in their operations. These types of licensees do not routinely see occupational exposures that would approach a 2 rem (20 mSv) per year level. Stakeholders were asked to go beyond the simple statement of opposition to a change in the dose limit, and provide perspectives on the relative impact of each of the options. In response, the stakeholders said that the use of an average and maximum value (Option 2) was particularly difficult because of the significant record keeping that would be needed to implement. For example, the NRC would need to return to the use of something equivalent to the previous versions of NRC Forms 4 and 5, in order to account for dose from previous years. While some nuclear utilities have protocols for sharing of individual occupational dose among the facilities, a requirement for accounting of doses across multiple years would exacerbate the problems of the transient worker groups that move from licensee to licensee, outage to outage in the reactor community.

Stakeholders also noted, as an argument against changing the dose limit, that Option 2 would make decisions on the basis for ALI and DAC calculations more difficult. The values in 10 CFR Part 20, Appendix B are intended to represent a level of intake of radioactive material, or airborne concentrations, that would be in compliance with the limits under standard conditions. If Option 2 were adopted, with an average and a maximum value of the occupational dose limit, then the values of ALI and DAC could be needed for both the average and maximum, complicating the Appendix B tables.

During the discussions with stakeholders, the stakeholders were asked to provide a rationale for why the existing limit should be seen as appropriate in light of the changes in radiation risk. Unfortunately, stakeholders did not provide any substantive suggestions. In fact, many stakeholders essentially dismissed the changes in radiation risk as either not relevant or non-existent. Nevertheless, these same stakeholders endorse the use of this same scientific information as the basis for making changes to tissue and radiation weighting factors.

Staff Analysis and Conclusions:

The staff has examined the need for a change in the occupational dose limit from several standpoints. First, is whether there is a scientific and risk informed basis that suggests that there should be adjustments in the radiation protection framework. As described in Enclosure 1, the NRC staff has concluded that there have been significant changes in radiation risk estimates, and the methodologies for recommending dose limits. These changes have been

developed by both national and international organizations. Given this information, the staff has concluded that there is a sufficient risk informed scientific basis to consider changes to the NRC's regulatory framework for occupational exposure. Such changes should logically reflect the risk implications of the limit, reflect a consistency in the rationale for occupational and public dose limits, and increase alignment with the ICRP recommendations, and the standards established in other nations.

Notwithstanding the above conclusion, the second question to be considered is whether the performance of licensees under the current NRC regulatory framework meets the more recent ICRP recommendations. The data available to the NRC staff indicates that the majority of individuals receiving occupational exposure are well within an annual average value of 2 rem (20 mSv). However, the data also indicate that there are small numbers of individuals who are receiving exposures greater than 2 rem (20 mSv) but less than 5 rem (50 mSv). Although data is not available, the statements made during the public workshops, by stakeholders in the industrial and medical sectors, lead to a conclusion that there may be individuals receiving exposures greater than 2 rem (20 mSv) every single year. Thus, there is the significant potential that their cumulative doses could legally reach the range which is not recommended.

The staff recognizes the strong viewpoints to keep the limit as it presently exists, and thus the staff carefully examined possible alternative methods to responding to the radiation risk information which would move in the direction of improving occupational protection while affording greater flexibility to licensees. Such an approach has, in fact, been suggested by a stakeholder in a formally docketed comment, and in discussions in some meetings with staff. The approach suggested was to strengthen the requirements for ALARA, in keeping with the ICRP recommendations, while leaving the occupational dose limit at its present value as the ultimate boundary for legal enforcement purposes.

An approach that puts an increased emphasis on ALARA planning, and some type of requirement for action if exposures were over some specified level, such as 2 rem (20 mSv) is, in fact, the approach currently utilized by the U.S. Department of Energy (DOE). The DOE regulations in 10 CFR Part 835, specify a 5 rem (50 mSv) limit for occupational exposure. The DOE also has in place an Administrative Control Level, as part of the required radiation protection program, set at 2 rem (20 mSv) per year. Approval for occupational exposures above the Administrative Control Level requires significant senior management approval before being allowed. Effectively, there are no occupational exposures greater than 2 rem (20 mSv) within the DOE system. Stakeholders similarly expressed the view that any secondary value would essentially become the limit. As described in Section 5, the staff carefully examined the possibility of establishing such a value as an alternative to a change in the dose limit, and concluded that the likely result would be a more prescriptive regulation that would be difficult for many smaller licensees to implement. Furthermore, the result would not ensure that exposures would be less than the suggested 2 rem (20 mSv) per year level.

External factors also have some impact on the trends in occupational dose performance by licensees. The trend to decreased individual exposure in the nuclear power reactor community is a result of a concerted effort to reduce exposures to ALARA. There is significant information sharing of best practices within this licensee community, and there are external factors such as industry ranking and insurance, which have provided a significant incentive to reduce exposures. As a result these licensees exhibit strong radiation control programs with detailed planning of activities that will incur radiation exposure. The approach used in these facilities is a

good example of the approach recommended by the ICRP for optimization of protection and the implementation of dose constraints, although those terms are not used.

Conversely, industrial licensees do not have the same type of culture of sharing of radiation protection best practices, and do not have external factors of comparative performance ranking across the industry that give an incentive to reduce exposures to ALARA. In fact, exposures are in many cases driven by the number of jobs. Further, many smaller licensees do not have radiation protection programs with the structure and planning approach typically utilized in large facilities, and do not have the resources available for striving to keep exposures well below the limits.

The staff believes that it is appropriate, and scientifically justified, to pursue changes to 10 CFR Part 20 to address occupational exposures that are near the current dose limit. Although recognizing the strong opposition by many stakeholders, the staff recommends that a reduction in the occupational TEDE 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.

The staff believes that a provision, such as that currently in the regulations for planned special exposures, and the provision that allows licensees to apply for prior authorization to operate at a higher public dose limit (10 CFR 20.1301(d)), has the potential to mitigate some of the impacts of the reduced dose limit, and provide flexibility for implementation on a case by case basis. The staff recommends against stating the limit as an average and maximum value (as recommended by the ICRP) because of the significant record keeping and reporting that would be needed to implement such a regulation. Given the current distribution of occupational dose, most licensees would not need the flexibility for occupational doses above 2 rem. The staff does not, at this time, recommend significant prescriptive additions to the ALARA provisions of the regulations, as these would seem to present an expensive and uncertain mechanism to reducing the exposure of higher dose individuals (see Enclosure 3, Section 5).

The recommended approach provides a performance based approach to eliminating exposures which are above the internationally recommended values, and which present an increasingly significant risk when they are received over many years. The approach would increase alignment of the NRC regulations with the international recommendations, and with the standards that have been adopted by many other nations. The approach would foster a global consistency which facilitates the increasing trans-boundary movement of workers across national borders. Further, the approach is responsive to a suggestion in the Integrated Regulatory Review Service (IRRS) report of 2010. The IRRS mission which reviewed the NRC regulatory program for reactors, noted the ongoing NRC staff effort to consider possible changes to the NRC regulatory framework, and suggested that alignment be increased with international recommendations and standards[1]. The NRC staff would, in moving forward with this recommendation, seek to obtain specific feedback on impacts and implications, and be able to engage different stakeholder communities using draft language to develop the regulatory basis and regulatory analysis for a proposed rule.

[1] The IRRS is an international peer review conducted under the auspices of the IAEA and is designed to strengthen and enhance the effectiveness of the national regulatory infrastructure of a country. Consideration is given to both regulatory technical and policy issues, with comparisons against IAEA safety standards and where appropriate, good practices elsewhere. The U.S. NRC IRRS report can be found at ADAMS No. ML110630400.

During the March 27, 2012, conference call with representatives of State Radiation Control Program Directors, there was support for the staff's proposal. One State noted that there were small groups of licensees or registrants that were getting doses greater than the ICRP recommended dose limit. The State went on to support the new dose limit and work with the small group of licensees regarding compliance alternatives. Another State noted that the ICRP recommended average and maximum limits might not provide sufficient flexibility in the short term to accommodate licensee needs, but agreed that this was a topic that needed additional discussion as recommended by the NRC staff.

Note that the staff has not considered a lifetime limit, which is part of the underlying basis for ICRP's recommendations. The Commission has previously disapproved of a lifetime limit, as discussed in the FRN for the final rule for the 10 CFR Part 20 revision in 1991. A lifetime limit is also difficult to implement operationally, which is why annual limits have been used, both here and abroad. The complications of tracking individual exposure across more than one year, which was the case with the old 5(N-18) provision[2], have resulted in some countries, particularly in Europe, moving to a single limit of 2 rem (20 mSv). The same considerations argue against use of the NCRP's recommendation, which was 1 rem (10 mSv) times the age in years (as in a 100 year old person would have 100 rem (1 Sv)).

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may feel the need to modify their programs, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

3) Occupational Limit for the Lens of the Eye

Summary of Staff Recommendation:

- Reduce limit to at least 5 rem (50 mSv) Lens Dose Equivalent (LDE) per year, and continue to develop regulatory basis.

Options Presented for Stakeholder Discussion:

1. No change, NRC limit would remain at 15 rem (150 mSv) per year.
2. ICRP recommendation of 2 rem (20 mSv) average over 5 years, with 5 rem (50 mSv) max in a year.
3. Single value of 5 rem (50 mSv) or 2 rem (20 mSv) per year.

[2] Prior to the 1991 revision of 10 CFR Part 20, the dose limit consisted of a quarterly limit of 3 rem (30 mSv), with an additional that the total occupational dose not exceed 5 rem (50 mSv) times the individuals age minus 18. So for an 18 year old individual the total occupational dose was not to exceed 5. For a 30 year old individual, the total occupational dose was not to exceed 60 rem. To demonstrate compliance, licenses therefore needed to have a record of the individual's total occupational dose. An annual limit, in contrast, does not require knowledge of occupational exposure from previous years, which greatly simplifies record keeping.

Supporting Information:

A statement by the ICRP in April 2011 recommended a reduction in the annual limit for the lens of the eye from 15 rem (150 mSv) to an average of 2 rem (20 mSv) per year with a maximum value of 5 rem (50 mSv). The recommendation was based on the compilation of scientific evidence that radiation induces cataracts at cumulative levels of approximately 50 rem (500 mSv), rather than the previously understood threshold of several hundred rem. The current NRC limit for the lens of the eye is 15 rem (150 mSv) per year.

Induction of a cataract is considered by the ICRP to be a "tissue reaction" effect with induction occurring at levels greater than the specified threshold value. For "tissue reactions," the severity of the effect is considered to be proportional to the accumulated dose above the threshold value. This model is in contrast to the model for cancer induction, which is modeled as a "stochastic" effect, where increasing the accumulated dose is assumed to result in a proportional increase in the probability of the effect. Evidence of a lower threshold for the induction of the effect is therefore evidence suggesting a reduction in the limit, in order to avoid accumulated doses which would cause the effect to occur.

The dose to the lens of the eye will be very close to the effective dose if there is not significant shielding to the body, or to the eyes. This is particularly true for gamma exposures, where the differences in the dose calculated at 0.007 cm (shallow dose equivalent), 0.3 cm (lens dose equivalent), and at 1 cm (deep dose equivalent) are not large. For other types of radiation, such as soft x-rays, beta particles, there is a more substantial difference that might need to be taken into account. So for many situations, such as industrial radiography, most reactor exposures, etc., a change to a value lower than the effective dose would mean that lens of the eye was the most restrictive requirement. Further, in these situations, it is not likely that a separate measurement of lens dose would be needed. Dosimetry processors today utilize algorithms to estimate lens dose based on the measured deep dose equivalent.

There are some situations where shielding comes into play. For example, when shielding is provided for the torso of the body, the dose to the lens of the eye will be the same as the deep dose measured above the shielding, but greater than the effective dose that would be calculated for the individual. This is particularly the case for interventional radiology and cardiology, where the routine use of leaded aprons results in the effective dose being much lower than the reading of a badge worn outside the apron. In this case, the lens dose would be an issue unless leaded glasses with side shields are used.

The IAEA had essentially completed the process for revising their Basic Safety Standards for Radiation Protection when the ICRP statement and recommendation became available. Member states of the IAEA were afforded an opportunity to comment on a change to incorporate the new recommendations. While a number of comments were provided to the IAEA that are similar to the comments raised by stakeholders during the NRC public comment period, the IAEA decided to move forward and incorporate the new recommended limit for the lens of the eye into the final version approved by the IAEA Board of Governors in September 2011.

Stakeholder Views:

The issue of possible changes for the limit on dose to the lens of the eye was not part of the early engagement process conducted by the staff. The ICRP made its new recommendation in April 2011. The topic was not a subject of discussion during the facilitated public workshops.

Stakeholder feedback to a solicitation of comments in the summer and fall of 2011 (76 FR 53847; August 30, 2011) provided a range of views. Several stakeholders agreed that the limit should be reduced from the present value. For example, an Agreement State supported the reduction in the LDE limit to 2 rem (20 mSv) per year, but noted that demonstration of compliance could be a problem if the LDE limit were to be less than the TEDE limit. Another stakeholder stated general support for aligning the NRC regulations to the ICRP recommendations, but did not provide specifics. One stakeholder even suggested that the change was overdue, because the increased incidence of cataracts has been known for some time.

Some comments received have been cautiously supportive of some change, but not the ICRP recommended values. A nuclear power licensee stated that a change to a single value of 5 rem (50 mSv) would be appropriate, and not entail significant costs. This same stakeholder indicated that the ICRP approach of an average and maximum value would be much more costly to implement, with the significant administrative costs to track and record the average dose over multiple years. Another commenter stated that a lens dose limit of 15 rem (150 mSv) per year is too high to provide a reasonable margin of safety. This commenter, however, also suggested that a lens dose limit of 2 rem (20 mSv) per year is overly cautious and may necessitate substantial changes in workflow, staff scheduling, increased costs, and other burdens.

Another commenter stated that the medical uses of radiation, particularly interventional radiology and cardiology, were the most likely to have significant exposure to the lens of the eye. Individuals in these fields commonly wear personal protective equipment, such as lead aprons, to shield the trunk of the body from the radiation field. The result is a dose to the lens of the eye which is greater than the calculated effective dose. The commenter went on to note that while these procedures are not under NRC jurisdiction, a move by States to modify their requirements would result in the States regulation of machine produced radiation in the same way as for byproduct material.

Other stakeholders did not support a change in the LDE limit from the current NRC requirement. For example one nuclear power licensee stated that the calculated LDE value rarely exceeds the TEDE dose estimate, and thus no change was necessary. This stakeholder further stated that the administrative control level established at their facility at 3 rem (30 mSv) had never been approached unless the administrative control level for TEDE of 1 rem (10 mSv) was also approached. Another stakeholder suggested that a low LDE limit could result in considerable follow up of monitoring measurements, which could detract from other ALARA efforts.

An Agreement State indicated that their operating experience did not justify a reduced dose limit. The State also indicated that a reduced limit might not be realistic for interventional medical personnel. The commenter stated that the imposition of reduced dose limits may result in certain individuals not consistently wearing lens of eye dosimeters to avoid recording exposure, resulting in an unmonitored dose.

Another commenter suggested that there was no scientifically convincing evidence that adults permitted a maximum of 15 rem (150 mSv) to the lens of the eye annually have any significantly increased evidence of cataracts. The commenter questioned the comparison of patients who have had radiation therapy or Computed Tomography (CT) scans to those who have not had them as an appropriate control group. According to this commenter, if exposure to other drugs, genetic differences and other possibly contributing factors are not considered, these comparisons are made more questionable. The commenter urged the NRC to compare patients who received radiation therapy with significant eye protection to those who did not, and patients who had CT scans with significant eye protection to those who did not, to determine any significant differences in cataract incidence.

Concerns were also raised about the comparability of the endpoint, specifically a cataract in the eye vs. the endpoint for effective dose limitation, which is morbidity and mortality from cancer. Contributing to these concerns is the fact 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 exposure. For example, a commenter from a nuclear power licensee suggested that changing the LDE dose limit appears to be out of alignment with the risk and severity for which the basis of the limit was established. According to the commenter, this would equate a deterministic endpoint of cataracts to that of a stochastic effect such as cancer. The commenter also believes that this recommendation requires further analysis based on the following concerns associated with this change: 1) The mechanism for radiation induced cataracts following low dose fractionated exposures is not well defined; 2) it is unclear how frequently radiation opacities might advance to visual impairment; 3) evidence is accumulating that both dose and latency play a role in developing conditions, but the latency period tends to be quite long and inversely related to dose; and 4) because cataract extraction rates are not well documented for occupational situations, it is difficult to judge the impact of radiation dose on the ability of the worker to perform his/her duties. The commenter said current limits for LDE were established at a period of time when cataracts were considered to be a more debilitating disease. The recommendation from the ICRP to lower the limit to the lens of the eye for cataracts does not appear to consider the current understanding of the severity, frequency of natural occurrence of cataracts, nor the actual impacts to an individual with cataracts.

Staff Analysis and Conclusions:

The staff has examined the stakeholder feedback, and the underlying technical and scientific issues. The staff believes there is an appropriate and scientifically justified basis to recommend that the impacts of a reduction in the dose limit for the lens of the eye to a single value of 5 rem (50 mSv) be explored in greater detail. The staff supports continued dialogue with stakeholders on the key issues to develop a regulatory basis for a proposed rulemaking.

Two key areas will need further discussion as part of the preparation of the regulatory basis for a proposed rulemaking. The first is the implications of establishing a value consistent with the limit for effective dose. The staff is aware that this issue will be particularly important to certain segments of the medical community, such as interventional radiology and interventional cardiology, where it is routine to provide shielding to the torso by the use of leaded aprons. These activities are not conducted under NRC jurisdiction, because they normally do not include exposure from byproduct material under the Atomic Energy Act. The staff would, under this

recommendation, work closely with the States through the Organization of Agreement States and the Conference of Radiation Control Program Directors to examine these impacts.

A second issue which requires further discussion is how the prevention of cataracts should be viewed in comparison with the potential induction of cancer. The staff plans to take into account comments which were received by the IAEA during the member state consultation, which included a number of concerns regarding the relative impact of cataracts vs. cancer.

The staff's recommended approach would not completely align the NRC's regulatory framework with the ICRP recommendations. The staff is not convinced, at this time that a reduction to 2 rem (20 mSv) is justified from a scientific and policy perspective. Depending upon the outcome of the continued discussions with stakeholders and the scientific community, the staff would continue to hold the possibility of a reduction to 2 rem, as one of the options analyzed in the preparation of the regulatory basis.

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may need to modify their programs, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

4) Occupational Limit for the Embryo/Fetus

Summary of Staff Recommendation:

- Change requirement to 100 mrem (1 mSv) applicable over gestation period remaining after declaration.
- Explore implications of applying over entire gestation period.

Options Presented for Stakeholder Discussion:

1. No change, retain 500 mrem (5 mSv) over gestation period.
2. ICRP recommendation of 100 mrem (1 mSv) applied to period after declaration.
3. Some other single value.

Supporting Information:

The ICRP recommendations for the embryo or fetus of an occupationally exposed female are reflective of an approach whereby the protection afforded is generally consistent with the level of protection provided for a member of the public. With the 2007 ICRP recommendations, this protection takes the form of recommending that an embryo/fetus be limited to no more than a dose of 100 mrem (1 mSv) over the remaining pregnancy following notification of the licensee or employer by the female occupational worker. The ICRP recommendation does not include a requirement for a retrospective assessment of the dose received prior to the declaration. The recommendations of the NCRP have remained at 50 mrem (0.5 mSv) per month. The staff is aware that the NCRP is currently preparing a report on Health Effects of Radiation on the Gamete, Embryo, Fetus, and Nursing Infant.

The current requirements of 10 CFR Part 20 (as set forth in 10 CFR 20.1208) provide for a limit of 500 mrem (5 mSv) during the pregnancy. The limit becomes effective upon a formal declaration to the licensee, and any exposure prior to the declaration must be assessed to determine the allowable exposure for the remainder of the pregnancy (see 10 CFR 20.1208(d)).

The current limit in 10 CFR 20.1208 reflected an alignment with the older limit for members of the public (5 mSv or 500 mrem). The change in the public dose limit to 100 mrem (1 mSv) was not accompanied by a corresponding change in the limit for the embryo/fetus of a declared pregnant woman.

Note that the individual's right to choose whether or not to declare, and when to declare, is voluntary[3]. The licensee is under no obligation to apply the limit for the embryo/fetus if there has not been a declaration.

Stakeholder Views:

Feedback was mixed from stakeholders to possible changes in the provisions. Many licensees indicated that they had no problems complying with the present requirements. Furthermore, many stated that their response to a declaration of pregnancy was to accommodate the individual in such a way that there was essentially no exposure for the duration of the pregnancy. For some categories of licensees, such as industrial radiography, it was noted that the proportion of women in the field had been historically low, although this was changing. Thus, a revision to a limit as recommended by ICRP may not cause significant concerns.

Some types of licensees, for example in nuclear pharmacies, indicated that the routine annual exposures are reported to be on the order of several hundred mrem (several mSv). For these licensees, the existing requirements for the occupational exposure of an embryo/fetus do not pose an operational issue because normal activities do not pose the possibility of exceeding the dose to the embryo/fetus. These licensees indicated that a reduced limit of 100 mrem (1 mSv) could pose a potential impact, depending on when an individual chose to declare her pregnancy.

Some medical stakeholders expressed concerns that a regulatory change adopting the ICRP recommendation may require modifications to the design of their facilities. These stakeholders indicated that their facilities were designed using conservative assumptions and based on a 500 mrem (5 mSv) dose criterion. These stakeholders report that they have not seen any impacts with the 500 mrem (5 mSv) level, such as having their primary care physicians stop procedures because they are reaching the 500 mrem (5 mSv) limit.

In addition, some stakeholders have expressed the view that the 100 mrem (1 mSv) value should be applied to the entire pregnancy, just as the current requirements apply to the entire pregnancy, in order to assure adequate protection.

When asked about the impacts of the present system, where there is a retrospective assessment of dose to the estimated date of conception, licensees indicated that they have been able to provide any necessary accommodations, and that there have not been significant impacts. The requirement for a retrospective assessment is well understood, and the staff did not receive any comments which addressed the possible reduction in burden if the requirement

[3] See definition of "declared pregnant woman" in 10 CFR 20.1003.

for a retrospective analysis were removed. As noted above, the ICRP recommendation does not include a requirement for a retrospective assessment of dose received by the embryo/fetus prior to the declaration of the pregnancy.

One of the issues discussed was the potential for a variable degree of protection when the requirements are only applied after a formal declaration. For example, if an individual chooses to declare relatively late in the pregnancy, the ICRP recommendation could actually mean that a greater dose could be accumulated than would be allowed under the current NRC regulation. This is because the ICRP recommendation does not include a provision for retrospective assessment, and the recommended limit only applies to the remainder of the pregnancy. Conversely, a declaration early in the pregnancy could be more restrictive. A stakeholder noted that the current NRC requirements also contain a restriction (50 mrem (0.5 mSv) on the additional dose that can be received after declaration, if the retrospective assessment indicates that the exposure before declaration already exceeded the 500 mrem (5 mSv) limit for the pregnancy. In this situation, a change to the 100 mrem (1 mSv) ICRP recommendation, applied after declaration, would, according to the stakeholder, not seem to pose a substantial impact, and in fact would be less restrictive.

Several stakeholders indicated that a more restrictive limit could result in an increase in individuals choosing not to declare their pregnancy, in order to ensure their continued employment. This issue was raised specifically in the medical context, where it was stated that medical students, residents, etc. would not want to have any impacts on achieving their degree and requirements. Some stakeholders went so far as to suggest that the requirements could result in an inappropriate bias in the selection of female applicants. Statements were also made that there could be an increase in non-compliance, with individuals choosing not to wear proper dosimetry, etc. Other stakeholders noted that such decisions are always a personal decision, and expressed a view that it was important that the rule provide protection equivalent to that provided to any other member of the public.

Another issue raised was the limits of detection for routine monitoring dosimetry. For many typical thermo-luminescent dosimetry systems (TLD), the minimum detectable exposure is in the range of 10 mrem (0.1 mSv). If an individual declared early in her pregnancy, it would be a challenge to actually monitor her exposure with sufficient precision to ensure compliance. The staff recognizes that this may be an issue in some situations, but also notes that dosimetry methods are available which would allow for sufficient monitoring to ensure compliance with the rule. In particular, newer electronic systems are sensitive down to approximately 1 mrem (10 μSv). This issue needs continued evaluation if the staff moves forward to develop a regulatory basis.

Similar to the comments on the TEDE limit, some stakeholders stated that reducing the dose limits may result in law suits because such a reduction would imply that declared pregnant occupational workers have been exposed to unsafe levels of radiation.

Overall, stakeholders stated that they preferred to continue with the existing requirements, which they were familiar with, rather than changing the limit to the ICRP recommendation.

Staff Analysis and Conclusions:

The issue of the dose limit for the embryo/fetus poses both technical and policy issues. Both the present NRC regulatory requirements and the ICRP recommendations are triggered when an occupational worker declares her pregnancy.

A unique feature of both limits is that the actual dose that could be received by an embryo/fetus is not a fixed number. Irrespective of whether there is a requirement for a retrospective assessment or only application of a limit to the dose after the declaration of pregnancy, the total dose to an embryo/fetus is dependent upon the dose received before declaration. With the current formulation in 10 CFR 20.1208, if the dose already received exceeds 500 mrem (5 mSv), or is within 50 mrem (0.5 mSv) of that limit at the time of declaration, then the allowable exposure is restricted to an additional 50 mrem (0.5mSv). The approach recommended by the ICRP would allow 100 mrem (1 mSv) in the same situation.

In a situation in which the accumulated dose to an embryo/fetus is less than 400 mrem (4 mSv) prior to declaration, the current rule would allow for a dose up to a total of 500 mrem. The ICRP recommendation would limit the added dose to 100 mrem, irrespective of the previously accumulated dose. For this scenario, the ICRP recommendation is a more restrictive requirement.

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 align the regulatory requirements to the scientific information available that the embryo/fetus is more sensitive to radiation and align the NRC regulations to the ICRP recommendations. The present regulations are inconsistent at the present time because the limit for a member of the public is 100 mrem (1 mSv) but the limit for an embryo/fetus is 500 mrem (5 mSv).

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may modify their programs and facilities, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

5) ALARA Planning

Summary of Staff Recommendation:

- Continue with existing general requirement for ALARA.
- Consider development of additional regulatory guidance, based on ICRP recommendations.

Options Presented for Stakeholder Discussion:

1. No change, existing ALARA requirements.
2. Add requirement for ALARA planning values as part of optimization of protection.
3. Specify a maximum value for ALARA planning.

Supporting Information:

The current 10 CFR Part 20 requires that licensees develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities. It also requires, to the extent practical, procedures and engineering controls to minimize occupational doses and doses to members of the public.

The ICRP, in Publication 103, emphasizes the optimization of protection, and organized its recommendations to focus on optimization in all exposure situations. It also recommended the use of "constraints" in planned exposure situations as a prospective tool in the planning of optimization.

Industry experience at nuclear power plants indicates that an effective implementation of ALARA is the best way to ensure compliance with the regulations, and further improve radiation protection. Exposures at civilian nuclear power plants are low because ALARA is emphasized and is part of the organizational culture. In fact, there are also external financial and public perception drivers, because the information on occupational and public exposures is publicly available, and is utilized by groups such as the Institute for Nuclear Power Operations and the American Nuclear Insurers as one of the rankings of the utilities and the plants. There are no similar internal or external set of drivers in the materials uses of radioactive material.

The NRC regulation at 10 CFR 20.1101(b) states that each NRC licensee "shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Thus the current 10 CFR Part 20 does not include an explicit requirement to plan activities to optimize radiation protection (ALARA planning), or to establish ALARA planning values as part of the radiation protection program. Although not required, ALARA planning is routinely found in commercial power reactor operations, but is not necessarily as commonplace in the programs of other types of licensees. The staff notes that enforcement citations in this area have not been made against the regulation. Instead, citations have been against specific license conditions, where such conditions exist.

The staff pursued discussion with stakeholders for several reasons. Fundamentally, the staff wished to determine if it is appropriate to provide the framework for ALARA in the regulations, rather than rely on a patchwork of license conditions, in order to foster a clear and consistent approach for all types of licensees. Such an approach could increase alignment with ICRP recommendations. Furthermore, this approach was seen as a possible alternative mechanism for reducing or eliminating the occurrence of occupational exposures that approach the dose limits.

Stakeholder Views:

Stakeholders were consistently opposed to the ICRP term "constraint." They were also consistently opposed to additional requirements for ALARA, with some indicating that it was difficult, or impossible to plan radiation protection. Stakeholders were also concerned that any numerical values would become de facto limits that must be met.

A power reactor stakeholder stated that every job in the plant is planned with an estimate of what that job is going to entail from a dose perspective, with goals which are somewhat less

than the estimate. According to this stakeholder, the collective radiation exposure has been on the decline in the United States for the last 15 - 20 years because of these ALARA techniques.

Another stakeholder stated that doses from portable gauges are extremely low, making it difficult to formalize constraints in their radiation protection programs. In this regard, most doses for portable gauge users are probably less than that which is minimally detectable. This stakeholder opposes the need for a constraint.

A commenter argued that the NRC should not adopt a wholesale approach to ALARA. This commenter argued that each radiation protection program should be reviewed individually to analyze the application of ALARA and of constraints.

An industrial radiography stakeholder stated that applying the ALARA concept has resulted in extra training and on-the-job observation. According to this commenter, the ALARA concept is very well received by employees. However, other industrial radiography stakeholders stated that it is difficult to plan ALARA activities and one went so far as to say that it was not possible to plan ALARA. The reasons cited are the unique environment of industrial radiography, where conditions and working areas are constantly changing, and the workload that must be accomplished to meet contractual obligations.

A number of industrial and medical stakeholders stated that any numerical values for planning radiation protection activities would become limits. They cited, as an example, the current requirement for a constraint on the airborne effluents of non-reactor facilities, where the requirement is to report if the effluent exceeds the value, and take corrective action to prevent recurrence. They indicated that this set of requirements made the constraint a limit because effluents had to be kept below the value.

A stakeholder representing a fuel fabricator reiterated that the current ALARA requirements are the effective way to reduce dose. According to this commenter, reducing the annual limit from 5 rem (50 mSv) to 2 rem (20 mSv) will not have any effect on managing the facilities' dose.

A stakeholder stated that the NRC's regulatory guides for ALARA requirements have been helpful for issues such as protecting pregnant occupational workers. The commenter recommended that the NRC develop an ALARA guideline which would provide licensees examples of how the ALARA program should be run. Therefore, this stakeholder recommends that the NRC issue such a regulatory guide rather than amending the NRC's regulations.

One stakeholder, in response to discussions about the occupational dose limits and ALARA, provided a proposal which would add requirements for ALARA planning, mandatory use of planning values, and reporting of situations in which the planning value was exceeded.

Staff Analysis and Conclusions:

The staff began the stakeholder outreach process with the possibility that strengthening ALARA could be an alternative approach to the reduction in the dose limits recommended by ICRP, particularly in the case of exposure of individuals approaching the dose limit. On several occasions, the staff outlined a possible approach where there could be explicit planning for ALARA as part of the radiation protection programs, a requirement that licensees establish and implement ALARA planning values for their activities, and a requirement that the maximum

acceptable ALARA planning value for individual occupational exposure be 2 rem (20 mSv). Licensees would need to translate the ALARA planning value into more specific, task or job planning, as appropriate for their activities. A similar proposal was made by one of the stakeholders.

Internationally, the discussion continues on the appropriate ways to incorporate the concept of constraints, or planning values, into regulatory programs. The IAEA has added a requirement to establish constraints as part of the International Basic Safety Standards. Similar requirements have been present in drafts of the European Directive that would update the European Basic Safety Standards. Notwithstanding these requirements, there continues to be discussion about how such provisions would be implemented and inspected.

The staff recognizes that any specification of a numerical value, as a planning value in ALARA programs, could become a de facto limit without careful specifications of the expectations of both the licensee and the regulator. During the stakeholder process it became clear that a great deal of work would be needed to construct language for regulations and guidance which might be acceptable.

The staff notes that ALARA cannot be a “one size fits all” requirement. Each licensed use presents its own set of hazards and opportunities for radiation protection, and licensees have a wide range of sophistication where it comes to the radiation protection program. The use of planning values, increased review of activities and circumstances causing exposure, and higher level management approval of any doses approaching or exceeding a planning value presupposes a relatively well established program and predictable working environments. While this is certainly the case in the nuclear power community, it is not the case for many industrial and other uses.

Further, the proposals discussed would not guarantee that individual occupational exposures greater than 2 rem (20 mSv) or some other planning value, would not continue. Unless the numerical value became a de facto limit, licensees would have the ability to justify continuing exposures on the basis of their analysis.

Thus, the staff has concluded that the ICRP recommendations, if implemented for ALARA planning, would result in a prescriptive set of requirements that could be difficult to implement for many licensees. Furthermore, the requirements would not guarantee the intended regulatory outcome of ensuring that higher occupational doses did not continue. There would also be the significant challenge to establish such a system and expectations across all of the Agreement States and NRC in a consistent, predictable and transparent manner. A major question would be the degree of compatibility that would be assigned, and the actions to be taken during inspection.

In light of these discussions, the staff believes that the international recommendations for ALARA should not be adopted as regulatory requirements and that it is more appropriate to propose that the limit be changed, as described in Enclosure 3, Section 2. With the existing requirements in 10 CFR Part 20, the NRC could develop additional guidance for improving ALARA implementation, which builds on existing industry experience as one way for licensees to continue to demonstrate compliance with the 10 CFR Part 20 ALARA requirements.

6) Protection of the Environment

Summary of Staff Recommendation:

- No change to current approach.

Options Presented for Stakeholder Discussion:

The topic of protection of the environment was not presented as a set of options during the stakeholder dialogue process. Nevertheless, the topic was discussed in a number of presentations made by NRC staff, and during the facilitated workshops.

Supporting Information:

In SRM-SECY-08-0197, the Commission agreed with the staff and the Advisory Committee on Reactor Safeguards (ACRS) that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment. The Commission also agreed with the ACRS that there is no evidence that the current set of radiation protection controls is not protective of the environment, and that the NRC should not develop separate radiation protection regulations for plant and animal species. The Commission directed the staff to continue to monitor international developments in this regard and keep the Commission informed.

The ICRP recommendations in Publication 103 discuss protection of the environment, and indicate the ongoing work to develop a framework in which 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 most recently published report is "Environmental Protection: Transfer Parameters for Reference Animals and Plants," ICRP Publication 114. The report focused on the approaches used to model the transfer of radionuclides through the environment, and detailed an approach to calculating generic radionuclide uptake into plants and animals, as part of ICRP's framework to assess dose impact of radioactivity on nonhuman species.

Stakeholder Views:

The topic was not initially presented as a formal topic of discussion with stakeholders, but some discussions did take place. Feedback generally affirmed the currently stated Commission position that additional regulatory standards were not necessary.

Staff Analysis and Conclusions:

The staff recommends that it continue to monitor, and interact with the various international organizations and efforts developing tools and methodologies for assessment of doses in the environment. The staff believes that 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. Thus the staff continues to believe that there is no need for additional standards, and does not plan to pursue the issue as part of its regulatory basis for a proposed rulemaking.

7) Units of Radiation Exposure and Dose

Summary of Staff Recommendation:

- Consider modification of 10 CFR Part 20 to reflect the current NRC metrification policy to list the dose units in SI first, with English in parenthesis.

Options Presented for Stakeholder Discussion:

The issue of units for radiation exposure and dose, specifically the use of the SI units was not one of the issues outlined for stakeholder discussion at the start of the outreach process. Nevertheless, the question was raised a number of times by various stakeholders.

Supporting Information:

On August 23, 1988, Congress passed the Omnibus Trade and Competitiveness Act (the Act), (19 U.S.C. 2901 et seq.), which amended the Metric Conversion Act of 1975 (15 U.S.C. 205a et seq.). Section 5164 of the Act (15 U.S.C. 205a) designates the metric system as the preferred system of weights and measures for United States trade and commerce. The Act also requires that all Federal agencies convert to the metric system of measurement in their procurements, grants, and other business-related activities by the end of fiscal year (FY) 1992, "except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms, such as when foreign competitors are producing competing products in non-metric units"[4].

Executive Order (EO) 12770, "Metric Usage in Federal Government Programs," was signed by the President on July 25, 1991. Its purpose is "to implement the Congressional designation of the metric system of measurement as the preferred system of weights and measures for the United States trade and commerce." Further, the EO directs all executive branch departments and agencies "to take all appropriate measures within their authority to carry out the provisions of this order."

In 1985, the NCRP called for a gradual adoption of SI units in the United States over a 5-year transition period (NCRP, 1985). More recently, in 2008 the National Institute of Standards and Technology (NIST) discouraged the use of the curie, roentgen, rad and rem (NIST 2008). In February 2012, the Health Physics Society issued a final Position Statement on the "Exclusive Use of SI Units to Express Radiological Quantities (see http://hps.org/documents/SIunits_ps025-0.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…."

In response to these actions, the NRC published a metrication policy statement for comment in the *Federal Register* on February 10, 1992 (57 FR 4891). A final policy statement was then published on October 7, 1992 (57 FR 46202), which also called for the NRC to assess the state of metric use by the licensed nuclear industry in the United States after 3 years to determine whether the policy should be modified. As a result, the staff contacted members of various industrial and standards groups to determine their view of the NRC policy. On September 27,

[4] 15 U.S.C. 205b(2).

1995 (60 FR 49928), the NRC published a request for public comment on its existing policy to learn if any modifications to the policy were needed. Following review of comments, the staff concluded that no changes to the Commission's metrication policy were needed.

A practical approach to using the metric system is one that is both consistent with the intent and direction of the Act and does not introduce safety concerns or result in an economic burden to licensees or applicants. This type of approach would result in the use of the metric system by those licensees and applicants for whom the use of the metric system presents no economic disadvantage and no safety detriment to the public.

The Commission's policy on metric system conversion remains as stated in the *Federal Register* (of October 7, 1992, 57 FR 46202), as updated by the Commission's policy statement of June 12, 1996. Pursuant to the 1992 policy, the NRC supports and encourages the use of the metric system of measurement by the licensed nuclear industry. In order to facilitate the use of the metric system by licensees and applicants, beginning January 7, 1993, the NRC began to publish the following documents in dual units: new regulations, major amendments to existing regulations, regulatory guides, NUREG-series documents, policy statements, information notices, generic letters, bulletins, and all written communications directed to the public[5]. The NRC policy further directs that documents specific to a licensee, such as inspection reports and docketed material dealing with a particular licensee, will be in the system of units employed by the licensee. Furthermore, all event reporting and emergency response communications between licensees, the NRC, and State and local authorities will be in the English system of measurement[6]. The Commission stated in its June 1996 policy statement that it does not intend to revisit this policy unless it is causing an undue burden or hardship (61 FR 31169, 31171, June 19, 1996).

Stakeholder Views:

In a number of the stakeholder interactions, representatives from various groups asked if the use of the SI units would be part of any revision to the NRC radiation protection regulatory framework. They stated that this was another factor in aligning the NRC's regulatory framework with the international recommendations. They also gave a number of areas in which SI units are seen as the primary units.

Some stakeholders, such as the Health Physics Society (HPS), have included this change both in comments during meetings and as a recommendation in written comments. They noted that the rest of the world uses the SI units exclusively. As noted above, the HPS issued a final Policy Statement in February 2012. Essentially all of the scientific literature uses SI units, having been adopted by the HPS and other scientific journals. Furthermore, these stakeholders stated that the differences in units can create issues of miscommunication.

Other stakeholders, such as those in the radio-pharmacy industry, noted that their business required the use of SI units because of the global movement of materials. These stakeholders suggested that it would be an advantage to be able to use SI units exclusively.

[5] 57 FR at 46203.

[6] 57 FR at 46204

Staff Analysis and Conclusions:

The use of SI units vs. the English system of measurement continues to be a point of dialogue. The staff recognizes the interest on the part of some stakeholders for a more uniform recognition of the SI units. However the staff also recognizes that there are significant issues in moving further towards alignment with the SI units. The same public communication and emergency response communication issues remain as they were in 1995. These issues were highlighted during the response to the Fukushima event, where there was confusion resulting from the use of different units.

Another significant factor will be interactions with other Federal agencies and the States. A move to increasing the use of the SI units would need to be in concert with a general move in that direction across the entire radiation protection community. Without such an agreement, it is not likely that such a change should be made. For example, one State noted that they did not support changing to SI units, and that their current practice of stating both units (SI in parenthesis) would continue. This matter would obviously need to be explored in detail with stakeholders if the Commission agrees that the staff should pursue this policy direction.

It is not clear, on the basis of stakeholder interactions to date, whether portions of the licensed community are now suggesting that there is burden or hardship issues which could warrant a re-examination of the current metrication policy. One suggestion was to simply reverse the ordering of the dual units from the existing format for 10 CFR Part 20, consistent with the current policy statement. The current 10 CFR Part 20 was issued before the metrication policy, and thus is formatted with the SI units in parenthesis. Other NRC regulations have instances in which the SI units are listed first, with the English units in parenthesis.

The staff recommends that discussions with stakeholders continue, to understand further the needs and implications of a change in the metrication policy. The results of the assessment would be provided to the Commission when the technical basis for rulemaking was completed.

8) Reporting of Occupational Exposure

Summary of Staff Recommendation:

- Explore with stakeholders the specific benefits and impacts of requiring additional categories of licensees to report occupational exposure.
- Work with Agreement States to identify possible methods to increase the availability of information to facilitate coordination.

Options Presented for Stakeholder Discussion:

The topic of reporting of occupational exposure was not part of the original list of topics included in the solicitation of stakeholder feedback.

Supporting Information:

Under the requirements of 10 CFR 20.2206(a), seven categories of licensees are required to provide reports each year of individual occupational exposure. These categories include nuclear power reactors pursuant to 10 CFR 50.21(b) or 10 CFR 50.22, industrial radiography

pursuant to 10 CFR Parts 30 and 34, fuel processing, fabrication and reprocessing pursuant to 10 CFR Part 70, high level radioactive waste pursuant to 10 CFR Parts 60 or 63, independent spent fuel storage installations pursuant to 10 CFR Part 72, radioactive waste under 10 CFR Part 61, and processing or manufacturing for distribution pursuant to 10 CFR Parts 30, 32, 33, or 35 for specified quantities of byproduct material. Licensees who are under jurisdiction of an Agreement State are required to report as required by that State, and are not under any requirement to report to the NRC.

During the stakeholder interactions, and the staff effort to develop estimates of possible impacts of possible changes, the lack of consistency in reporting of occupational exposure was identified. For example, at the present time there are no medical licensees that are required to report. As further discussed in Enclosure 4, this lack of information has made the development of realistic impact assessments difficult.

Information that is reported to the NRC is held in the Radiation Exposure Information Reporting System (REIRS). This data base can be analyzed in a variety of ways, and the NRC staff annually produces NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities." The report for calendar year 2010 is currently being finalized.

Information currently provided under the requirements is by individual, and is considered as Personally Identifiable Information. The REIRS database and access is properly controlled for such information.

Stakeholder Views:

During the staff's consultation with stakeholders, questions have arisen on the actual doses received by some categories of occupationally exposed workers. Because these groups do not have to report their exposures to the NRC, either because there is no requirement, or because they are a licensee of an Agreement State, it has been very difficult for the staff to develop estimates of the impact of various proposals. Some stakeholders have suggested that additional categories be required to report exposures. These statements were general statements of support, and did not provide specific advantages of reporting, other than noting that such reports would allow for more accurate assessments of impacts.

Other stakeholders have opposed possible requirements for reporting. Some of these stakeholders, for example portable gauge users, stated that there was no reason for their exposures to be reported because the doses received are very low. Other stakeholders oppose the possible requirements because of the added costs to provide such reports.

During the March 27, 2012, conference call with representatives of State Radiation Control Program Directors, there was support for the staff's proposal to explore the implications of reporting. State representatives agreed that an issue of concern is the total exposure an individual may be receiving while concurrently working at more than one facility.

Staff Analysis and Conclusions:

There are several potential benefits of reporting of occupational exposures for additional categories of licensees. The first benefit is the availability of data to assess the impact of

regulatory requirements on occupational radiation protection performance of licensees. The NRC staff has experienced difficulties in developing the information needed to accurately assess the current distribution of occupational doses for some segments of use, because reports are not required. This same type of information is also used to develop trends in exposures in response to various questions or events.

A second benefit is the availability of data to support possible inspections, where the presence of significant exposures, even within the limits, may result in a performance based evaluation of the radiation protection program. In addition, movement towards a national level database provides the opportunity to determine if individuals, who may work for multiple licensees across multiple jurisdictions, are approaching or exceed the occupational dose limit. At the present time there is no mechanism for gaining insights into this situation, except for individuals working within the nuclear power industry. A more unified reporting requirement and database could support inspection of licensees, and an understanding of trends that could be used in information notices and other generic communications to groups of licensees.

The NCRP Publication 160 indicates that there are individuals who exceed 5 rem (50 mSv) per year in a number of categories of exposure, but there is no specific analytical database to confirm these statements. If true, the NCRP information would point to compliance issues with the existing occupational exposure requirements.

The staff notes that an increase in the reporting would be consistent with international calls for dose registries.

Countering the potential benefits of reporting are the potential costs to report, and the effort that would be needed to integrate reports received from multiple jurisdictions. Under the present 10 CFR Part 20 requirements, the dose record for each person is provided to the database. Most of the submissions are now done electronically. For those categories of licensees who do not currently report, there would be the additional burden of providing the records of individual dose to the appropriate regulatory organization, either the NRC or the applicable Agreement State. These records are currently required to be maintained, but not reported. While the increment in cost to provide an electronic copy of their records to the regulatory agency is small, the aggregate cost across all individuals and additional licensees could be substantial. Additional costs would arise with respect to the sharing of information in a properly controlled manner so that an integrated set of data is available for assessment, or to provide the results of particular types of assessments to a regulatory organization to meet their specific needs or questions.

The staff believes that there is merit to adding to the categories of licensees that are required to provide annual reports of individual occupational exposure. However, there may be little reason for licensees using only small sources to provide such reports. While the simplest approach would be to simply require that the exposures that are monitored by licensees be reported, alternatives of how to specify the appropriate risk informed pool of licensed uses would need to be pursued. The staff is well aware that many individuals are routinely monitored who do not explicitly meet the requirements for monitoring. This monitoring is done as a good practice, to ensure that exposures are not somehow overlooked, and in many cases as part of guarding against liability issues.

At the present time, Agreement State licensees are not required to provide reports to the NRC, and there is no collaboration between the Agreement States and the NRC that would allow for the establishment of a national registry. In some cases, it appears that the Agreement States are not getting reports. Thus, the Agreement States are crucial in exploring the benefits, impacts, and any approach to increased reporting.

9) 10 CFR Part 50, Appendix I

Summary of Staff Recommendation:

The objective of the proposed revision is to align the dosimetry basis of 10 CFR Part 50, Appendix I regulations with 10 CFR Part 20 by incorporating current developments in radiation protection principles and advances in radiation dosimetry that have occurred since the issuance of ICRP Publication 2 over 50 years ago. This approach was consistent with the prior version of 10 CFR Part 20 up to 1991, but is no longer consistent with current 10 CFR Part 20. Accordingly, the staff recommends that up-to-date scientific methodology and terminology be applied in a consistent manner as opportunities are available to update other portions of the NRC's regulatory framework. Staff recommends that the concepts of effective dose, and the numerical values that support the 2007 ICRP recommendations, be used as the baseline of information supporting an update of the dosimetry basis of 10 CFR Part 50, Appendix I design objectives and guidance.

Options Presented by the Staff:

- No change, do not revise the dosimetry basis of 10 CFR Part 50, Appendix I design objectives and guidance, or
- Revise the dosimetry basis of 10 CFR Part 50, Appendix I and guidance to reflect an update of 10 CFR Part 20 based on the ICRP 2007 recommendations.

Supporting Information:

Since 10 CFR Part 50, Appendix I was promulgated in 1975, significant changes have occurred in radiation protection science and methodologies in calculating doses. The dosimetry basis utilized by 10 CFR Part 50, Appendix I was consistent with the version of 10 CFR Part 20 prior to 1991. As revised in 1991, 10 CFR Part 20 changed the methodology by implementing dosimetry concepts of ICRP Publication 26 and ICRP Publication 30. However, Appendix I and guidance documents (e.g., Regulatory Guide 1.109 and others) were not changed, and, therefore, are still based on ICRP Publication 2 dosimetry concepts.

Currently, the implementation of 10 CFR Part 50, Appendix I design objectives and ALARA provisions is well established and the power reactor industry has extensive operational experience in demonstrating compliance. The concern is that the use of an outdated dose calculation methodology, in expressing separate doses for the whole body and critical organs using ICRP 2 dosimetry, is inefficient for both licensees and the NRC. In anticipation of future nuclear power plant applications, the removal of inconsistencies between 10 CFR Part 20 and the dosimetry basis of 10 CFR Part 50, Appendix I design objectives would be an important modernization of the regulatory process and eliminate confusion in the current dual regulatory requirements.

The staff is recommending that the dosimetry basis of Part 50, Appendix I be aligned with the dosimetry concepts and dose calculation methods of ICRP 103. This alignment would be coordinated with the parallel update of 10 CFR Part 20. This approach provides the means to standardize the regulatory framework and avoid the need to calculate doses using two different methods. This option supersedes the staff's prior recommendation presented in SECY-08-0197. In that option, the staff had recommended that the dosimetry basis of 10 CFR Part 50, Appendix I requirements be aligned to that of the current 10 CFR Part 20 (based on ICRP 26 & 30) as a backup provision in modernizing Part 50, Appendix I. While Option 2 of SECY-08-0197 would be an improvement over the current situation, Option 2 of that paper is not recommended here since it would still leave the underlying dosimetry basis and dose calculation methodology of 10 CFR Part 50, Appendix I to an outdated dosimetry concept.

Over the past decade, there have been discussions with stakeholders and interested parties about updating the basis of 10 CFR Part 50, Appendix I design objectives and its supporting guidance documents to be consistent with the dose methodology used in 10 CFR Part 20. For example, issues have been raised in light of new applications for early site permits, design certifications, and combined construction permits and operating licenses submitted under 10 CFR Part 52.

Stakeholder Views:

The general preference with most stakeholders from the nuclear industry is the option to align the 10 CFR Part 50, Appendix I scientific information with the proposed alignment of 10 CFR Part 20. These stakeholders noted that because the current regulations provide adequate protection, any change to Appendix I should be consistent with any changes that are made to 10 CFR Part 20 as related to any regulatory alignment with the recommendations of ICRP Publication 103. A stakeholder stated that from a practical standpoint, most utilities that plan to build new plants would prefer a total alignment with 10 CFR Part 20, 10 CFR Part 50, and ICRP Publication 103. Another stakeholder noted that if the underpinnings of 10 CFR Part 50, Appendix I were to comply with ICRP Publication 103, it would probably align U.S. NRC regulations well with the international community.

A stakeholder from the nuclear industry stressed that updating the science is an opportunity, not the driver for the change and update to 10 CFR Part 50, Appendix I. Another stakeholder stated the advantage of revising 10 CFR Part 20 and 10 CFR Part 50, Appendix I at the same time, is that the NRC could address the revisions to its regulations in an "all in one" approach versus having to do it in two different rulemakings.

Other stakeholders questioned the potential change to 10 CFR Part 50, Appendix I, noting that 10 CFR 50.34a specifically states that the Appendix I numerical criteria and compliance with ALARA portion or elements or provisions of 10 CFR Part 50, Appendix I, are not a safety standard. These stakeholders further stated that it has, nevertheless, become a de facto standard for implementation. These stakeholders assert that these provisions are design criteria used for the review of systems for new reactors that are being licensed, but those same criteria are applied as limiting conditions of operation of operating plants. Thus, these stakeholders do not believe that a change should be made to 10 CFR Part 50, Appendix I.

Several questions were raised on options being considered by the staff. One stakeholder asked if the alignment and harmonization of 10 CFR Part 50, Appendix I, 40 CFR 190, and other

related rules with the ICRP guidance would cause reactor effluents to go down for current power plants. According to this commenter, if the answer to this question is no, then this is an intangible exercise, or an exercise to promote math and science. They indicated that they do not see any justification for this regulatory action unless it can be shown that reactor effluents have to go down to meet the new standards.

A stakeholder representing the nuclear power industry agreed with a revision of the regulatory guidance supporting 10 CFR Part 50, Appendix I (e.g. Regulatory Guides 1.21 and 1.109), which includes revising and importing all dose conversion factors and then evaluating assumptions that are equally important to dose, such as usage factors. Other stakeholders noted that they also support an expanded scope, which revises all of the parameters and dose conversion factors, updated with current state-of-the-art information, or whatever information is available in the literature, and then leaving intact basic environmental models, for example, atmospheric and aquatic dispersion. Some stakeholders stated that utilities with a large number of power plants versus a single entity with one or two power plants may have a greater benefit from revising the procedures and computer codes used in calculating doses to members of the public.

Staff Analysis and Conclusions:

The staff recommends a revision to the design objectives of 10 CFR Part 50, Appendix I and associated regulatory guidance for the purpose of making Appendix I and the associated guidance consistent with the dosimetry basis of 10 CFR Part 20. Under the staff's recommendation, the revised regulations and guidance would retain the current numerical design criteria of Appendix I, but would redefine the dose criteria as ED or TED to be consistent with new 10 CFR Part 20 definitions of doses and nomenclature – see discussion in Enclosure 3, Section 1 on proposed changes to 10 CFR Part 20 methodology and terminology. No changes are contemplated to 10 CFR 50.34a and 50.36a regulations as these requirements do not invoke dose criteria. The proposed revision offers several advantages as it provides an opportunity to integrate the guidance on technical issues associated with 10 CFR Part 50, Appendix I requirements with that of 10 CFR Part 20. Moreover, the proposed revision provides the means to standardize the regulatory basis, impart a common underpinning on the principles of optimization and limitation of doses, standardize dose calculation methodologies, and facilitate compliance with regulations and simplify reporting requirements.

If approved by the Commission, the staff would continue to develop the regulatory basis necessary for a revision of 10 CFR Part 50, Appendix I. This regulatory basis would utilize the approach recommended for the update of 10 CFR Part 20 for consistency, and is expected to include a number of issues that are not connected with the update of methodology and terminology, as discussed in Enclosure 3 of SECY-08-0197. Enclosure 3 of that SECY paper outlines ramifications on regulatory programs and potential impacts on stakeholders and members of the public that would need to be evaluated in the development of the regulatory basis. As part of the regulatory basis, the staff would consider updating key regulatory guides and determine whether other supporting documents require revision, and describe the advantages and limitations to NRC programs and licensees, as discussed in Enclosure 4 of SECY-08-0197. Enclosure 4 of that SECY paper presents a preliminary list of technical guidance documents (e.g., a generic letter, regulatory guides, and NUREGs) and computer codes that would need to be evaluated in assessing the need and extent of any revisions.

The staff will prepare a regulatory analysis addressing potential costs and benefits with respect to all affected classes of licensees and applicants. The evaluation would also assess the impacts on implementation of the Reactor Oversight Process. The regulatory analysis will be separate from consideration of backfitting and issue finality (discussed in Enclosure 3, Section 10 below).

A review of current regulations and requirements indicates that there are a number of regulatory and technical overarching issues that would need to be considered in defining the most effective course of action. The staff would address whether to initiate the revisions of 10 CFR Part 20 and 10 CFR Part 50, Appendix I as two parallel rulemaking efforts with the implementation of the revised rules being synchronized to a common implementation date when all regulatory conforming changes and revisions of implementing guidance would be completed. The staff recommends that this effort be initiated on a parallel track with that of 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 into the Reactor Oversight Process.

10) Backfit Analysis

Summary of Staff Recommendation:

- 10 CFR Part 20 applies to various licensees and applicants who are protected by various backfitting provisions, including issue finality provisions in 10 CFR Part 52.
- Some provisions could be considered as redefinitions of adequate protection.
- Other provisions would require assessment of benefits and impacts.
- Quantitative analysis will not be possible in many cases, and qualitative arguments will be important in the consideration of benefits.

Supporting Information:

10 CFR Part 20 is applicable to a wide range of licensees and applicants. Some of these licensees and applicants are protected by backfitting and issue finality provisions, in 10 CFR 50.109; 10 CFR §§ 52.39, 52.63, 52.83, 52.98, 52.145, 52.171; 10 CFR Part 52, Appendices A, B, C, and D, Section VIII; § 54.37; 10 CFR 70.72; 10 CFR 72.62; and 10 CFR 76.76. Thus, the development of a proposed rule will require assessment of each affected class or licensee or applicant under the applicable backfitting and issue finality provisions in 10 CFR Chapter I.

The revision of 10 CFR Part 20, published in May 1991, concluded that the final rule provided a substantial increase in overall protection of public health and safety for both workers and members of the public. The Commission's conclusion rested on both quantitative and qualitative grounds. It is likely that a similar situation will exist with this current set of considerations.

Staff Analysis and Conclusions:

While some of the specific provisions could be considered to be adequate protection, it is unlikely that the entire package could be considered as such – at least under the current NRC

regulatory framework.[7] The staff can prepare a backfit analysis with quantifiable costs, but some benefits are in many respects unquantifiable and will need to be expressed in qualitative terms, as the Commission suggested may be done in a 1993 SRM for SECY-93-086.

For the proposal to adopt updated methodology and terminology there are substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology. These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by regulations, and the value of terminology that represents the updated science and which is used by many other nations.

A benefit in updates to 10 CFR Part 20 are that the demonstration of compliance is based on the current scientific information, and that the regulatory requirements are aligned with the ongoing staff practice to recognize appropriate, up-to-date approaches. It is also important to ensure that the methodology and factors used in dose calculations are a consistent set. For example, when the staff granted requests to use the methodology associated with the 1990 ICRP recommendations, one of the provisions was that the same methodology be used for the entire radiation protection program. This was to avoid a possible situation in which results from different systems were “cherry picked” as advantageous for one reason or another.

The benefit of consistently moving to the updated methodology across the entire NRC radiation protection framework is greater than that seen for 10 CFR Part 20 alone. As noted previously, 10 CFR Part 50, Appendix I uses even more outdated methodologies. For example, reactor licensees currently perform dose calculations using two different methods, one for compliance with 10 CFR Part 20 regulations (based on ICRP 26 & 30) and for compliance with Part 50, Appendix I regulations (based on ICRP 2), with some overlap in demonstrating compliance with EPA regulations under 40 CFR 190 and as implemented in 10 CFR 20.1301(e). As a result, power reactor licensees use methods and a process that are different from the requirements of other parts of 10 CFR Chapter I, are time consuming, and are difficult to explain to the public. In that regard, a move to a consistent methodology should lead to an increase in public confidence and transparency.

The benefits of updated methodologies are not quantitative in nature. Public confidence, transparency, scientific accuracy, predictability of requirements are all qualitative in nature, as is the benefit of the NRC regulatory system using the same modeling and assessment approaches used elsewhere in the world. It is possible, however, to have quantitative measures of costs. There will, in fact, be substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology.

These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by regulations, and the value of terminology that represents the updated science and which is used throughout the world.

[7] If the Commission were to adopt the Near Term Task Force Recommendation 1, then it may be possible that a greater set of provisions in the 10 CFR Part 20 and 10 CFR Part 50, Appendix I rulemaking, or possibly the entire rulemaking, could be considered to be adequate protection.

It is possible that the staff will conclude that, despite the flexibility afforded by the Commission in using qualitative consideration to support a finding of a "substantial increase in protection," that the Commission will determine that such a finding cannot be made. In such an event, the Commission has several alternatives for moving forward to adopt the requirements. One possibility, discussed in the Commission's 1993 SRM, is that the Commission may make an "exception" (now termed an "administrative exemption") to the Backfit Rule. The Commission took this extremely rare action in its issuance of the Aircraft Impact Assessment Rule (74 FR 28112; July 9, 2009). However, another approach would be for the Commission to adopt amendments to the relevant backfitting requirements (including issue finality provisions in Part 52), which would specifically exclude the 10 CFR Part 20 and 10 CFR Part 50, Appendix I rulemaking from those backfitting provisions. The extent to which the modifications to 10 CFR Part 50, Appendix I are made applicable to existing power reactor licensees may also influence decisions regarding the approach to backfit.

The staff recommends moving forward to develop the regulatory basis for the recommended issues. As part of the discussion with stakeholders, the staff would develop the specific information necessary to prepare: (i) the documented evaluation supporting the adequate protection provisions, and (ii) the backfit analysis for those provisions which cannot reasonably be characterized as adequate protection, including the quantitative and qualitative factors to be considered in the determinations of a substantial increase in protection to public health and safety.

Examination of National and International Impacts of Adoption of ICRP Recommendations

Introduction

The U.S. Nuclear Regulatory Commission (NRC) staff has engaged in multiple domestic and international activities to obtain information on potential costs and impacts of the three options described in this Commission Paper. This enclosure summarizes the results of information-gathering efforts in support of delineating the options and impacts of moving the NRC's radiation protection standards toward greater alignment with recommendations outlined in the International Commission on Radiological Protection (ICRP) Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection." These efforts focused on identifying specific impacts, costs, benefits, and burdens of making changes to the NRC's radiation protection regulatory framework.

Dose limits

The NRC staff investigated potential impacts of making changes to the occupational dose limit by collecting and analyzing information about the actual dose distributions from NRC and Agreement State licensees. Technical reviews of historical occupational exposure records were conducted to assess potential impacts to changes in the existing annual occupational dose limit of 5 rem (50 mSv) and the lens of eye dose limit of 15 rem (150 mSv). Data was analyzed from several information sources, including the NRC's Radiation Exposure Information and Reporting System (REIRS) database[1], data maintained by commercial dosimetry vendors, discussions with industry groups, and data submitted from a limited number of Agreement States in response to the Office of Federal and State Materials and Environmental Management Programs (FSME) letter, FSME-2010-072, "Request to Provide Occupational Radiation Dose Data from Industrial Radiography and Nuclear Pharmacy Licensees," dated August 6, 2010. This combination of data analyses allowed the staff to collect and analyze additional occupational exposure information that is not routinely obtained solely from NRC licensees. Although it captured the majority of NRC- and Agreement State-licensed facility categories, only limited occupational dose information for medical institutions was obtained by the NRC staff using alternative data collection methods because the REIRS database collects occupational exposure information for only a small sector of medical licensees (nuclear pharmacies). Also, this database does not include other facilities such as those regulated by the U.S Departments of Energy (DOE) and the Defense (DOD).

[1] The NRC licensee categories contained in the REIRS database are commercial nuclear power reactors; fuel processors (including uranium enrichment facilities), fabricators, and reprocessors; industrial radiographers; manufacturing and distribution of byproduct material (including nuclear pharmacies); and independent spent fuel storage installations. The Agreement State licensee categories are industrial radiographers; waste disposal service processing and/or repackaging; irradiators; well logging companies; sealed source facilities; measuring systems and portable gauge facilities; calibration services; veterinary (non-human) facilities; and other facilities. The Agreement State licensee information contained in REIRS was provided voluntarily by these licensees.

The number of individuals exceeding 5 rem/yr (50 mSv/yr) total effective dose equivalent (TEDE) in REIRS for NRC and Agreement State licensees is 21 for the 1994 to 2010 reporting period. The number of individuals exceeding 5 rem/yr (50 mSv/yr) to the lens of the eye (lens dose equivalent or LDE) during these years was also 21, as the TEDE is generally the same as LDE in most monitoring situations. Individuals exceeding 5 rem (50 mSv) TEDE have exceeded a regulatory limit and generally represent situations where an incident or accident has occurred, not during normal operating conditions or processes. Exceeding 5 rem (50 mSv) LDE is not in excess of the current regulatory limit of 15 rem (150 mSv) for LDE. Only one individual exceeded 15 rem (150 mSv) LDE from 1994 to 2010.

The staff's analysis indicates the number of individuals exceeding 2 rem/yr (20 mSv/yr) TEDE has decreased by 80 percent from a high of over 1,000 in 1995 to about 200 in 2010. Thus, 99.7 percent of individuals with measurable TEDE and LDE were below 2 rem/yr (20 mSv/yr) in 2010.[2] As a general trend, relatively few individuals in the nuclear power reactor category routinely exceed 2 rem/yr (20 mSv/yr), whereas individuals working in other licensee categories such as temporary job site radiography routinely exceed 2 rem/yr (20 mSv/yr) without a significant decrease in their reported occupational doses. For example, in the most recent reporting period (2010), 75 percent of the individuals exceeding 2 rem/yr (20 mSv/yr) were reported from industrial radiography licensees. Also, dosimeter readings above 1 rem (10 mSv) are typically associated with hospitals and medical clinics.

The staff continues to actively collect and analyze information about the actual dose distributions from NRC and Agreement State licensees to gauge the impacts of reduced dose limits at medical and other specific categories of non-reactor licensed facilities, such as industrial radiographers. The staff is preparing an update to the 1995 report, NUREG/CR-6112, "Impact of Reduced Dose Limits on NRC Licensed Activities," which will provide limited preliminary information on potential costs and impacts of reduced dose limits. The update is expected to be released later this year.

Historical Information on Costs and Impacts of Implementing ICRP Publication 60

The staff has sought information from domestic and international information sources to estimate the resources expended to implement the recommendations of International Commission on Radiological Protection (ICRP) Publication 60, "1990 Recommendations of the International Commission on Radiological Protection," as a possibly useful comparative tool for estimating the costs of implementing ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection." The intent of gathering this information was to supplement information obtained by FSME from various stakeholder workshops and *Federal Register* Notices regarding possible revision of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation."

In 2010 and 2011, 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. The survey includes information from 11 small and large countries from 4 continents with different

[2] For most occupational exposure situations, the dose to the lens of the eye will be the same as the TEDE. However, for some exposure situations, the lens dose may be higher than the TEDE.

economic conditions, thereby providing a reasonable but limited representation of current international experience in implementing ICRP Publication 60 recommendations. This survey was supplemented with supporting information from the European Commission on its draft impact assessment for the next EURATOM Basic Safety Standards Directive; information from the International Atomic Energy Agency concerning occupational exposures in interventional cardiology; and ICRP Publication 60 implementation considerations at a large European nuclear power licensee.

Although the survey was designed to obtain cost information from these supplemental information sources, it actually obtained little cost information because such data had not been acquired or retained. When ICRP Publication 60 was prepared in 1990, cost-benefit analyses in support of new regulations were typically not conducted in most countries. No survey participants assessed the no-action alternative of not implementing ICRP Publication 60, and no participant identified a reduction of cost resulting directly from ICRP Publication 60 implementation. Survey participants noted, however, that cost-benefit impact analyses will likely be required for implementation of ICRP Publication 103. These analyses have not been conducted to date.

Two countries (Canada and United Kingdom) reported additional costs for implementing ICRP Publication 60 that were associated with increased dose monitoring and upgraded dose registries. In Canada, the overall cost to implement new radiation protection regulations was 5.9 million CAD (46 percent is attributed to new security requirements), and the annual incremental cost was 4.5 million CAD (56 percent for new security and 22 percent attributable to the new ICRP Publication 60 dose limits). In the United Kingdom, the overall cost to implement new radiation protection regulations was 0.84 million GBP (about 2 million CAD) of which 78 percent is attributed to licensee costs and 12 percent to regulatory costs. The annual incremental cost was 1.2 million GBP (about 2.8 million CAD) of which 99.7 percent is attributed to licensee costs and 0.3 percent to regulatory costs.

Overall, occupational doses are trending downward since issuance of ICRP Publication 60, which can be attributed to more rigorous optimization programs and a reported increased focus on training and radiation protection by implementation of ICRP Publication 60. However, the trend of decreasing occupational exposures varies among countries and licensee category. Some countries, such as Norway and Canada, reported increased occupational exposures for medical staff.

All survey respondents have adopted the recommendations of ICRP Publication 60 and they expect only minor changes to existing radiation protection regulations to implement ICRP Publication 103. Regulatory topics that may require change are nomenclature, use of new weighting factors, optimization and use of constraints and reference levels, and new dose limits for the lens of the eye. However, survey respondents anticipated little change in the resources required of regulatory agencies to implement ICRP Publication 103. Thus, the overall cost impact of ICRP Publication 103 is expected to be minimal and less than that of ICRP Publication 60. A few European countries may analyze the no-action alternative as part of a regulatory impact assessment, but there will be little or no analysis of the cost of not implementing ICRP Publication 103 because the updated EURATOM Basic Safety Standards Directive will make ICRP Publication 103 mandatory in member countries. The European Commission's September 2011 draft impact assessment for the next EURATOM Basic Safety Standards

Directive did not contain quantitative cost information for the regulatory options evaluated for member country implementation.

The increased emphasis in ICRP Publication 103 on the use of dose constraints is expected to pose difficulties in countries that have not adopted the dose constraint concept but will be only a limited problem for countries that already use this concept. Significant problems are not expected with the implementation of new dose coefficients, calculation methods, and terminology. However, according to information provided by the International Atomic Energy Agency, compliance with wearing dosimeters may be an issue for the medical community.

In addition to the aforementioned efforts to obtain ICRP Publication 60 implementation costs from other countries, the staff also pursued collection of similar information from domestic sources. For example, the DOE revised its regulations for occupational radiation protection (10 CFR Part 835, 72 FR 31094; June 8, 2007) and radiation protection of the public and environment (Order O 458.1, February 11, 2011) to incorporate updated radiation dosimetry methodologies (ICRP Publication 68, "Dose Coefficients for Intakes of Radionuclides by Workers," and Publication 71, "Age- Dependent Doses to Members of the Public from Intake of Radionuclides: Part 4 Inhalation Dose Coefficients"). These methodologies are used to implement the recommendations of ICRP Publication 60.

Both of these relatively recent DOE rulemakings involved extensive stakeholder involvement over several years. DOE decided not to adopt all ICRP Publication 60 recommendations in these regulatory revisions. Most notably, DOE did not change the annual occupational dose limit from 5 rem (50 mSv) to the ICRP Publication 60 recommendation of 10 rem (100 mSv) over 5 years. However, for occupational exposures, DOE adopted an annual administrative control level of 2 rem (20 mSv) that requires administrative approval for higher occupational exposures, which functions similarly to the ICRP Publication 60 dose constraint concept. Also, DOE formally established dose constraints in Order O 458.1 for the release or clearance of property with residual radioactivity. Regarding costs for developing and implementing these regulations, DOE was not required to estimate or track costs as part of these rulemaking activities, so there is no summary information available on either DOE's costs for promulgating and implementing these regulatory changes or DOE operators' implementation costs.

Another potential source of domestic cost information on incorporating the radiation dosimetry methodologies of ICRP Publications 60 and 68 is the fuel cycle facility licensees regulated by the NRC. The staff tried to obtain information on actual costs incurred by the fuel cycle licensees when they adopted the updated ICRP methodology in their radiation protection programs during the 1990s. The fuel cycle licensees did not track this information, so no cost estimates are available of the licensees' cost to update their radiation protection programs. However, there were cost savings for implementing revised uranium dose coefficients associated with the ICRP Publication 68 methodology.

Similar to the approach used by NRC fuel cycle facilities, other Federal agencies have adopted portions of ICRP Publications 60 and 68 for radiation dosimetry purposes. For example, the Energy Employees Occupational Illness Compensation Program Act, administered by the U.S. Department of Health and Human Services' National Institute for Occupational Safety and Health (NIOSH), uses ICRP Publication 60 radiation weighting factors and updated ICRP models to calculate radiation doses to occupationally exposed workers. However, staff of the

Office of Nuclear Regulatory Research is not aware of NIOSH or any other Federal regulatory agency possessing cost information.

Based on the results of the information-gathering efforts to date on ICRP Publication 60 implementation costs, it is apparent that most countries, including the United States, did not conduct a comprehensive assessment of the costs of promulgating and implementing regulations, guidance, or licensee radiation protection programs because either this type of assessment was not required or regulators and licensees considered the costs sufficiently small that they were not worth tracking. Other possible explanations are that anticipated improvements in operational efficiencies were expected to offset implementation costs, regulators and licensees were afforded ample time for planned implementation, and that the net benefits of harmonization amongst countries were viewed as advantageous in comparison to implementation costs.

From the international perspective, implementation costs for ICRP Publication 103 are expected to be less than those for ICRP Publication 60 because there is no major change in the recommended dose limits between the two publications, excluding the April 2011 ICRP recommendations for a reduction in the annual limit for the lens of the eye. However, the NRC has not updated 10 CFR Part 20 to comport with ICRP Publication 60, so the costs associated with an update of 10 CFR Part 20 to either ICRP Publication 60 or ICRP Publication 103 may be similar, and higher than the costs expected by countries that have adopted ICRP Publication 60. A detailed comparison of the costs of implementing ICRP Publication 60 and Publication 103 is not possible at this time because the ICRP has not yet issued updated dose coefficients and biokinetic models corresponding to the recommendations in ICRP Publication 103. This information is essential for estimating potential changes to regulations, guidance, and licensee operations. It is expected that in comparison to other countries, NRC and licensee costs would likely be significantly higher because of the more comprehensive analyses required for NRC rulemakings.

Resource Estimates

Limited resources are currently included in the staff's business line rulemaking budgets for Fiscal Year (FY) 2012 through FY2013 which can be made available for stakeholder and interested party interactions and regulatory basis (previously referred to as technical basis) development for the two rulemakings recommended by the staff in Option 3. Table 1 provides a breakdown of the resources that have been budgeted for FY 2012 and included in the President's budget for FY 2013, respectively, for these rulemakings. The staff will address the budget for these rulemakings in future budget submittals using the Planning, Budget, and Performance Management (PBPM) review process once the Commission has issued its Staff Requirement Memoranda to this paper.

Table 1. Budgeted/Planned FY12 and FY13 Resources for Parts 20 and 50 Updates

Business Line	Part 20 Rulemaking				Part 50 Rulemaking			
	FY 2012		FY 2013		FY 2012		FY 2013	
	FTE	$k	FTE	$k	FTE	$k	FTE	$k
Materials Users	1.0	0	1.0	0	0	0	0	0
D&LLW	0.4	0	0.4	0	0	0	0	0
New Reactors	0	0	0	0	1.6	60	1.5	60
Operating Reactors	2.1	0	2.1	0	0.2	0	0.2	0
Corporate Support	0.3	0	0.1	0	0.2	0	0.2	0
TOTAL	3.8	0	3.6	0	2.0	60	1.9	60

In addition to the above rulemaking resources, approximately $400K is currently budgeted in FY2012 and FY2013 by the Office of Nuclear Regulatory Research to support the development of the technical basis for 10 CFR Part 20. These funds come from the Materials Users Business Line and the Operating Reactors Business Line.

Resource needs are anticipated to increase in future years as the staff completes the development of the regulatory basis for each rulemaking. The level of increase depends on the Commission direction. Tables 2 and 3 provide a rough preliminary estimate of the total resources that would be needed to execute each option for the 10 CFR Part 20 and 10 CFR Part 50, Appendix I rulemakings, respectively. Estimates are based on the assumption of regulatory basis development in FY 2013 through FY 2015, proposed rule development in FY 2016, and final rule development in FY 2017. The staff assumes that significant stakeholder dialogue and interactions would continue through the regulatory basis development, through the proposed rule and comment period, and into the final rule development. A more detailed schedule and resource estimate will be developed using the PBPM process following the Commission's direction.

Table 2. Resource Estimate vs. Staff Option for Part 20 Update

Option	FY 2013		FY 2014		FY 2015		FY 2016		FY 2017		TOTAL	
	FTE	$k	FTE	$k	FTE	$k	FTE	$k	FTE	$k	FTE	$k
1	0	0	0	0	0	0	0	0	0	0	0	0
2	3.6	400	1.0	400	1.0	400	2.0	500	2.0	500	9.6	1800
3	3.6	400	3.0	400	3.0	500	4.0	500	4.0	500	17.6	1900

Table 3. Resource Estimate vs. Staff Option for Part 50 Appendix I Update

Option	FY 2013		FY 2014		FY 2015		FY 2016		FY 2017		TOTAL	
	FTE	$k	FTE	$k	FTE	$k	FTE	$k	FTE	$k	FTE	$k
1	0	0	0	0	0	0	0	0	0	0	0	0
2	1.9	60	2.9	200	3.2	650	3.3	620	1.5	170	12.7	1700
3	1.9	60	2.9	200	3.2	650	3.3	620	1.5	170	12.7	1700

Note: Resources for FY2013 shown in Tables 2 and 3 for Options 2 and 3 are copied from Table 1 above