

**POLICY ISSUE
(Notation Vote)**

December 18, 2008

SECY-08-0197

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: OPTIONS TO REVISE RADIATION PROTECTION REGULATIONS AND
GUIDANCE WITH RESPECT TO THE 2007 RECOMMENDATIONS OF
THE INTERNATIONAL COMMISSION ON RADIOLOGICAL
PROTECTION

PURPOSE:

The purpose of this paper is to request Commission approval of the staff's recommended option regarding the revision of the U.S. Nuclear Regulatory Commission (NRC) regulations and guidance for radiation protection to address the Recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 103.

SUMMARY:

This paper provides the background and an evaluation of the 2007 recommendations contained in ICRP Publication 103, as they relate to possible implications for the NRC's regulations and guidance for radiation protection. The staff has developed regulatory options of moving, or not moving, towards greater alignment of the NRC regulatory framework with ICRP Publication 103. The staff recommends that the Commission approve the staff taking the next steps towards achieving a greater degree of alignment of NRC's regulations with the recommendations contained in ICRP Publication 103. The staff proposes to immediately begin engagement with stakeholders and interested parties, and initiate development of the technical basis and regulatory analysis information during FY 2009, FY 2010 and FY 2011 for possible revision of 10 CFR Part 20, and 10 CFR Part 50 and Part 50 Appendix I. Because certain materials necessary to finalize the technical basis will not be available until 2011 or later, the staff will provide specific recommendations for initiation of rulemaking once the technical basis has been developed after 2011.

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The Commissioners

The staff recommends that the technical issues identified in this paper will be the starting point for a dialogue with stakeholders and interested parties in order to better understand the impacts of moving towards greater alignment with ICRP Publication 103. Pursuing these discussions before the initiation of rulemaking will facilitate preparation of a more complete catalog of issues, options, and the technical materials needed for a proposed rule. The staff will provide the Commission with the results of the stakeholder and interested party interactions, the recommended scope of rulemaking, and the resources needed at the time it provides specific recommendations for rulemaking.

BACKGROUND:

On April 12, 2002, in a staff requirements memo (SRM) for SECY-01-0148, "Processes for Revision of 10 CFR Part 20 Regarding Adoption of 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 ICRP recommendations. However, the Commission disapproved the staff's proposal to develop a communications plan and a technical information base that would eventually be necessary for any contemplated rulemaking. ICRP Publication 103 (December 2007) contains the revised recommendations that are the latest in the series published by the ICRP.

10 CFR Part 20 provides the fundamental radiological protection regulatory requirements for NRC licensees. Through the existing compatibility criteria, the Agreement States have certain requirements 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, and was based primarily on the 1977 recommendations contained in ICRP Publication 26, and the public dose limit later reflected in the 1990 recommendations contained in ICRP Publication 60. Not all the recommendations contained in ICRP Publication 60 were incorporated into 10 CFR Part 20 in 1991 because those recommendations were not available during the public comment period for the proposed rule.

In 1991, some other portions of the regulatory framework (e.g. 10 CFR Parts 32, 50, 51, 61, and 72) were not considered or updated along with 10 CFR Part 20. Those portions not updated were primarily those in which explicit dose criteria were provided, rather than a cross-reference to 10 CFR Part 20. Consequently, the use of radiation protection concepts based on the 1958 recommendations contained in ICRP Publication 1, and the maximum permissible concentrations of radionuclides from ICRP Publication 2 (1959) are still required for some licensed activities. This is particularly the case for 10 CFR Part 50, Appendix I, dealing with effluents for operating power plants, current new reactor applications and early-site permits, and the next generation of nuclear plants. On the other hand, the NRC fuel cycle licensees requested and were authorized, on a case-by-case basis, to conduct licensed activities using the dose methodologies that have been revised by the ICRP since 1990. As a result there are three different generations of recommendations (ICRP Publications 1, 26, and 60), and corresponding methodologies for calculating radiation doses, that comprise various aspects of NRC's regulatory guidance and licensing programs that are in use today by various licensees. The staff notes that this situation is similar for other U.S. Federal agencies and the Agreement States where a similar spectrum of requirements exists.

On June 30, 2008, in SECY-08-0092, "Plans For Review of Radiation Protection Regulations In Light Of the New International Commission on Radiological Protection Recommendations," staff committed to provide the Commission with options in December 2008, for possible revision of the overall regulatory framework and to consider using the recommendations contained in ICRP Publication 103 to modify rulemaking proposals that are being developed.

DISCUSSION:

The radiation protection framework recommended by ICRP Publication 103 is, in most respects, similar to previous recommendations of the ICRP. The framework continues to be based on the fundamental principles of justification of exposures, optimization of protection, and limitation of dose. In particular, the numerical values of dose limits for occupational and public exposure are unchanged from the 1990 recommendations contained in ICRP Publication 60. Enclosure 1 provides a brief synopsis of the ICRP recommendations.

ICRP also assessed new scientific information, and provides new weighting factors for certain tissues and types of radiation and incremental improvements to reflect recent scientific understanding of the intake, distribution, retention, and elimination of radioactive material from the body. The staff recognizes that the ICRP is still in the process of preparing updated dose conversion factors by incorporating the new weighting factors for tissues and types of radiation, and the new metabolic models, and that the updated dose conversion factors will be available in subsequent ICRP publications. ICRP estimates that the computation of dose conversion factors for occupational workers, for the more commonly used radionuclides, will not be available until 2011. Dose conversion factors for members of the public may be available in 2012. A complete set of values, covering all radionuclides, may not be available before 2014. These dates impact the timing of any NRC revision to the radiation protection framework because the dose conversion factors are an essential underpinning for the Appendix B values in 10 CFR Part 20. Furthermore, the revised dose conversion factors are crucial to the completion of computer codes used for implementation of the regulations, including 10 CFR Part 50, Appendix I. As a practical matter, licensees, irrespective of the date of a rulemaking, will not be able to implement a revised rule until the new dose conversion factors are available, and they have been incorporated into procedures and software.

Other Federal agencies are also in the process of considering changes as a result of ICRP Publication 103. During the spring and fall 2008 meetings of the Interagency Steering Committee on Radiation Standards, the members shared preliminary views about the impact of ICRP Publication 103. The U.S. Environmental Protection Agency (EPA) indicated that it was examining the 2005 National Research Council report, Health Risks from Exposure to Low Levels of Ionizing Radiation, and ICRP Publication 103, with a view to updating the dose conversion factors presently contained in Federal Guidance Report No. 11, and then the cancer risk coefficients presented in Federal Guidance Report No. 13. The EPA does not use ICRP-derived dose conversion factors. Instead, EPA creates U.S. specific dose conversion factors based on U.S. census data which includes morbidity and mortality information related to cancer statistics for the U.S. population. EPA has not yet decided whether to update the Presidential Federal Guidance for Occupational Exposure, last issued in 1987. The U.S. Department of Energy indicated that it was continuing with previous plans to update certain portions of its regulations to align with ICRP Publication 60, and that it had not yet considered changes related to ICRP Publication 103.

Regulatory Options:

The staff has examined the current regulatory framework, and recognizes that a number of different areas are candidates for updating the regulations, the implementing guidance, and supporting technical codes and standards. The staff is presenting three principal options for revising the NRC radiation protection framework.

The first option is to make no changes to the existing regulatory framework. The second option is to update certain portions of the regulations, not previously revised, to conform to existing 10 CFR Part 20 concepts and quantities that are based on ICRP Publications 26 and 30. The third option is to begin the process of aligning, to a greater degree, the NRC's regulatory framework with the recommendations contained in ICRP Publication 103. Under this option, several factors come into play in developing approaches for proceeding, including: 1) the schedule upon which additional technical information will be available; 2) the need to revise certain regulations and address their implementation for licensing a new reactor; 3) the variety of other technical and policy issues that may be considered when various portions of the regulations are proposed for amendment; and 4) the availability of resources. These factors are described below in the discussion of regulatory and administrative options.

Option 1: No Action

The no action option will result in no changes being proposed to the existing radiation protection framework of 10 CFR Chapter 1. This option is based upon the fact that the current regulations provide adequate protection of public health and safety and are well understood by licensees, and that the impacts of changing the regulatory framework are not balanced by the benefits of updating scientific information and enhancing international consistency. That is to say that achieving better alignment of the framework with the recommendations contained in ICRP Publication 103 will not significantly improve public health and safety.

Under this option, no resources will be necessary for development of a technical basis for rulemaking, or for rulemaking activities. The staff will continue with previous plans to update Regulatory Guides as needed and appropriate.

The staff recognizes that there have already been challenges raised by industry and intervenor organizations to NRC's existing regulatory framework during the initial processing of new reactor applications. This, coupled with the benefits of enhancing international consistency, leads the staff to conclude that making no changes to the existing radiation protection framework is not the preferred option.

The staff notes that the nuclear power industry has stated a strong preference that NRC should update the regulatory structure of 10 CFR Part 50, Appendix I. The staff also notes that questions and concerns have been raised to various NRC senior managers by international organizations and regulators who advocated adoption of the recommendations of either ICRP Publication 60 or ICRP Publication 103. In the increasing globalization of activities, and the desire to harmonize requirements, movement towards alignment with the ICRP recommendations is an important component of aligning the NRC with our international counterparts.

Option 2: Update 10 CFR Part 50 and Appendix I

This option will consider revisions to 10 CFR Part 50 and Appendix I to Part 50 to align with the existing concepts and quantities in the current 10 CFR Part 20. This option, like Option 1, assumes that modifications to 10 CFR Part 20 are not warranted. Furthermore, it assumes that there is a sufficient regulatory rationale and technical justification for updating portions of the NRC regulations that were not updated when 10 CFR Part 20 was revised in 1991, to achieve consistency in approach.

Such an approach will advance the NRC's goal of achieving internal consistency of its regulatory requirements, but will not improve international consistency, in that the NRC's regulatory framework will remain based on concepts and quantities of ICRP Publications 26 and 30. This option would relieve some of the burden currently experienced within the power reactor community, in that those licensees will no longer need to use methods of ICRP Publication 2 (1959) to demonstrate compliance with the NRC regulations.

Under this option, resources will be devoted to developing the technical basis, regulatory analysis, and rulemaking for 10 CFR Part 50 and Appendix I to Part 50. This option will defer consideration of aligning other portions of the regulations at this time, and focus upon the more urgent needs of the power reactor community for updated and consistent regulatory requirements for licensing a new reactor. Other portions of the regulations that were not previously revised can be considered for revision when those regulations are being amended for other purposes, but resources will not be devoted to those actions at this time. Resources will be needed to update Regulatory Guides and supporting scientific and implementation codes.

At this time, approximately 0.5 Full Time Equivalent (FTE) has been budgeted within the Office of Nuclear Reactor Regulation (NRR) in FY 2009 and that about 0.5 and 1.0 FTE will be needed within the Office of New Reactors (NRO) for FY 2009 and FY 2010, respectively. Resources for FY 2011 and beyond would be developed as part of the budget preparation process. Rulemaking will be initiated upon completion of the technical basis, and the timing of this effort will not need to be connected to the current work of the ICRP. The specific resources that will be needed to support this rulemaking and associated guidance cannot be specified until conclusions have been reached upon the extent of the revisions that might be made to 10 CFR Part 50 and Part 50 Appendix I.

The staff notes that this option, while improving the internal consistency of NRC requirements, will not move the NRC towards a greater degree of alignment using current scientific concepts and quantities of ICRP Publication 103. Likewise, it leaves unanswered the requests and concerns from industry and international counterparts. Thus, the staff has concluded that this is not the preferred option.

Option 3: Align the radiation protection regulatory framework with ICRP Publication 103

Option 3 will begin the process of moving towards a greater degree of alignment between the regulatory framework of 10 CFR Parts 20 and 50 and Appendix I to Part 50 with the recommendations contained in ICRP Publication 103. This option is premised on the assumption that there are regulatory and technical justifications sufficient to begin the work necessary to eventually revise NRC regulations and guidance in order to incorporate updated recommendations, concepts, and quantities. While the current regulatory framework continues

to provide adequate protection of public health and safety, the current framework is not fully consistent with the objectives of the NRC Strategic Plan, as described below.

As proposed by the staff, this option will also defer consideration of aligning other portions of the regulations at this time, and focus upon the more urgent needs of the power reactor community for updated and consistent regulatory requirements for licensing a new reactor. Those other portions of the regulations, which continue to rely on ICRP 2 methodology, include portions of 10 CFR Parts 32, 51, 61, and 72. In the staff's analysis, these portions of the regulations will, in addition to requiring additional resources, open other issues for discussion which will detract from the focus needed to complete consideration of 10 CFR Part 20 and 10 CFR Part 50 and Part 50 Appendix I.

A revision of the regulations and associated guidance will provide an opportunity for increasing consistency with the NRC Strategic Plan by introducing a more realistic (risk-informed and performance-based) and scientifically up-to-date approach in licensing and regulating licensed facilities. Based on the consideration of technical issues and options presented below, the staff believes there are likely to be benefits from updating scientific quantities and information, refining the regulatory structure so as to further emphasize the fundamental principle of optimization, adding increasing structure and tools to a licensee's radiation control program, and simplifying the regulatory burden for the NRC and licensees.

Under this option, rulemaking will not be initiated immediately because the information needed for an adequate technical basis for rulemaking, and a regulatory analysis of benefits and impacts, is not yet available. Given the Commission's direction in SRM-SECY-01-0148 to not proceed with development of a technical information base that will eventually be necessary for any contemplated rulemaking, information now needs to be developed for the significant issues and options identified by the staff. The staff believes that this is the appropriate time to undertake these activities, so that when the necessary dose conversion factors are available from ICRP, a rulemaking can be considered. Furthermore, potential impacts of the significant issues and options on various licensees have not been fully assessed. The staff's ability to formulate an appropriate proposed rulemaking will be greatly enhanced by open dialogue with stakeholders and interested parties to identify issues of concern, the options available to address those concerns, and the technical information needed to support preferred approaches. This dialogue is best initiated before specific decisions on the part of the NRC staff have been made.

This option will require only the expenditure of resources that will be necessary to initiate stakeholder and interested party interactions to develop, identify, and elaborate on regulatory issues and options, and to initiate development of the technical basis needed for rulemaking and a regulatory impact assessment. Limited resources are currently included in the budgets for FY 2009 and FY 2010 which can be made available, through the planning, budgeting, and performance management (PBPM) process for stakeholder and interested party interactions and technical basis development.

Specifically, approximately 1 FTE in FY 2009 and 1 FTE in FY 2010 can be made available within the Office of Federal and State Materials and Environmental Management Programs (FSME), 0.5 FTE is available for NRO in FY 2009, and 1 FTE will be identified by NRO through the PBPM process for FY 2010. The Office of Nuclear Regulatory Research (RES) has budgeted \$100K and 0.2 FTE for FY 2009 and \$300K and 1.2 FTE for FY 2010, respectively, to

support rulemaking activities. Approximately 0.5 FTE has been budgeted within NRR in FY 2009.

The staff recommends that the Commission approve Option 3, and direct the staff to begin the process necessary to develop the basis for a rulemaking that will move towards aligning and updating 10 CFR Part 20 using the recommendations and scientific quantities and concepts described in ICRP Publication 103. The staff will provide the Commission with a recommendation to initiate rulemaking once the technical basis has been developed. The staff will, at that time, also provide the Commission with the results of the stakeholder and interested party interactions, the recommended scope of rulemaking, backfit and implementation issues, and the resources necessary. The actual date for a recommendation on rulemaking will be dependent on the availability of the appropriate technical basis for the proposals being made. In interactions with stakeholders and interested parties, the staff will explore the implications and issues associated with initiation of a rulemaking before the complete technical basis for all numeric values in Appendix B to 10 CFR Part 20 become available.

The staff further recommends that the Commission approve a parallel technical basis development that will support a rulemaking for selected changes to 10 CFR Part 50 and Appendix I to Part 50 to bring both into a greater degree of alignment with current international recommendations for radiation protection as contained in ICRP Publication 103. Work can be initiated more quickly on a rulemaking that will revise 10 CFR Part 50 and Appendix I to Part 50 because some issues are not dependent on ICRP dose conversion factors. The development work, described in the technical options below, can proceed in coordination with the work effort in revising 10 CFR Part 20, but the completion of a technical basis supporting a revision of Appendix I to Part 50 and promulgation of a revised Appendix I to Part 50 will be coordinated with that of 10 CFR Part 20 to ensure consistency between the two sets of regulatory requirements.

The staff believes outreach will be an important key to successful development and implementation of the rulemakings and that the approval of Option 3 will give the staff an opportunity to engage in extensive stakeholder and interested party outreach. The staff will solicit stakeholder and interested party identification of potential conflicts and attempt to gain an understanding of any unintended consequences related to the drafting and implementation of the rulemakings. Such discussions will include 10 CFR Part 50 and Appendix I to Part 50 issues when engaging stakeholders and interested parties of the nuclear power reactor industry.

The staff envisions that initial outreach efforts will consist of meetings, workshops, and forums which will take place during FY 2009, and will be followed by additional meetings in FY 2010 to further elaborate and validate issues, options, and impacts. The staff will convene facilitated discussions, and will attempt to leverage existing meeting opportunities to the extent practical, such as meetings of various professional societies and industry organizations. The issues provided in the technical options below, and the enclosures to this paper will be used to facilitate these discussions.

The staff considered the use of an Advance Notice of Proposed Rulemaking (ANPR), but believes that the information in the enclosures is sufficient for initial stakeholder and interested party dialogue, and that the time needed to prepare an ANPR could delay the start of the initial discussions.

The key stakeholders and interested parties have been identified as including the general public, NRC licensees, other Federal agencies, State and local governments, Indian Tribes, industry organizations, industry workers, technical societies, and citizen groups. These interactions will need to include all of the various licensees, including power reactors, test and research reactors, fuel cycle facilities, and the various byproduct materials activities, as well as extensive discussions with Agreement States. The staff is already aware of several opportunities in early calendar year 2009 where initial discussions could be held with stakeholders and interested parties. Interactions with the international community will also be appropriate to understand the direction, scope, and timing of the ongoing revisions of international standards. Further, staff will work with other Federal agencies to encourage consideration of updates to their regulations to facilitate a consistent approach.

Technical Options: 10 CFR Part 20

The staff believes that many of the provisions in 10 CFR Part 20 do not warrant changes and updates, because the majority of ICRP Publication 103 is similar to ICRP Publication 26 on which the greater part of 10 CFR Part 20 is based. However, the staff has identified a number of technical areas in which modifications should be considered to increase alignment of the regulatory structure with international recommendations, increase the focus of radiation protection upon optimizing radiation exposures, add structure to licensee radiation protection programs to assist in identifying and reducing exposures that approach regulatory limits, and allow for a more risk-informed regulatory framework. Enclosure 2 provides a brief summary of several key issues that have been identified, and the principal options that might be considered.

Technical Options: 10 CFR Part 50

In 1975, the NRC adopted the “As Low as Reasonably Achievable” principle in regulating radioactive gaseous and liquid effluents from nuclear power plants. The requirements and numerical guidance are contained in Part 50 and Appendix I, respectively, but the design objectives are not radiation protection standards under 10 CFR Part 50.34a. Over the past decade, there have been discussions with stakeholders and interested parties about updating the basis of Appendix I dose 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 reactor applications. Enclosures 3 and 4 provide details of the staff’s evaluation of these issues.

IMPLEMENTATION:

There are several factors, including the milestones for development of dose conversion factors, updates, revisions of certain key regulatory guides and computer codes, and the schedules for licensing and construction and initial operation of new power reactor facilities, that suggest that a target for completion of activities may be 2015 – 2016 for both 10 CFR Parts 20 and 50. The staff notes that if initiation of rulemaking is delayed until the final publication of all dose conversion factors, the implementation by licensees may not occur until 2020 or later. The staff’s preferred approach described in Option 3 above will support such an ultimate time frame for implementation.

COMMITMENT:

The staff proposes to immediately begin engagement with stakeholders and interested parties, and initiate development of the technical basis and regulatory analysis information during FY 2009, FY 2010 and FY 2011 for possible revision of 10 CFR Part 20, and 10 CFR Part 50 and Part 50 Appendix I. Because certain materials necessary to finalize the technical basis may not be available until 2011 or later, and because of the limited resources budgeted for FY 2009 and FY 2010, the staff will provide specific recommendations for initiation of rulemaking in another Commission paper once the technical basis has been developed after FY 2011.

RECOMMENDATIONS:

The staff recommends that the Commission approve the staff's recommended Option 3. The staff will initiate development of a technical basis and engage in stakeholder and interested party outreach to identify issues, options, and impact information. The staff will provide specific recommendations for initiation of rulemaking once the technical basis has been developed. The staff will also provide the Commission with the results of the stakeholder and interested party interactions, the recommended scope of rulemaking, backfit and implementation issues, and the resources necessary. The actual date for a recommendation on rulemaking will be dependent on the availability of the appropriate technical basis for the proposals being made.

The staff recommends that this paper, and the enclosures, be made publically available to facilitate discussions with stakeholders and interested parties. The staff believes these activities are a high priority, given the significant amount of work necessary to develop a technical basis. This upfront work will position the NRC to initiate rulemaking when the ICRP completes development of the dose conversion factors.

RESOURCES:

Limited resources are currently included in the budgets for FY 2009 and FY 2010 which can be made available, through the PBPM process for stakeholder and interested party interactions and technical basis development. Specifically, approximately 1 FTE in FY 2009 and 1 FTE in FY 2010 can be made available within FSME, 0.5 FTE is available for NRO in FY 2009, and 1 FTE will be identified by NRO through the PBPM process for FY 2010. RES has budgeted \$100K and 0.2 FTE for FY 2009 and \$300K and 1.2 FTE for FY 2010 to support rulemaking activities. Approximately 0.5 FTE has been budgeted within NRR in FY 2009.

The staff will prepare proposals for budget assumptions, and resources, as part of the FY 2011 budget submittal. The staff recognizes that a large resource effort over a number of years will be necessary to completely align all of the regulations, guidance, and supporting calculation codes and materials, and that such an estimate cannot accurately be provided until a greater understanding of the specific issues and regulatory provisions is understood as part of the proposed stakeholder and interested party interactions. This information will be provided at the time the staff provides its recommendations for rulemaking.

COORDINATION:

The Office of Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the General Counsel has reviewed this

Commission Paper and its enclosures and has no legal objection. Informational briefings were held with the Advisory Committee on the Medical Use of Isotopes and with the Advisory Committee on Reactor Safeguards.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. Synopsis of ICRP Publication 103
2. Details of Technical Options and Issues for Revision of 10 CFR Part 20
3. Details of Technical Options for Revision of 10 CFR Part 50 and Appendix I Regulations and Regulatory Guidance for Light Water-Cooled Nuclear Power Reactors
4. Listing of NRC Guidance Documents Potentially Subject for Update in Support of the Revision of 10 CFR Part 50 and Appendix I Regulations for Light Water-Cooled Nuclear Power Reactors

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