

NUCLEAR REGULATORY COMMISSION
Request for Comments on the Potential Changes to the US Nuclear
Regulatory Commission's Radiation Protection Regulations and Guidance
and Notice of Public Meetings
[NRC-2009-0279]

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of Public Meeting and Request for Comment.

SUMMARY: The NRC is conducting a series of public meetings, in the format of facilitated roundtable workshops, to solicit early public input on major issues associated with potential updates to NRC's radiation protection regulations and guidance in light of recommendations presented in the International Commission on Radiological Protection (ICRP) Publication 103 (2007). To aid in that process, the NRC is requesting comments on the issues discussed in this notice. The NRC has not initiated rulemaking on this subject, and is seeking early input and views on the benefits and impacts of options to be considered before making any decision on whether to proceed with a rulemaking. Each meeting will include a panel of participants, selected in a convening process to represent the diversity of stakeholders for these issues, including the various uses of radioactive materials licensed by the NRC. In addition to the panel, the NRC is encouraging observation and participation by all interested individuals. The meeting agenda will specifically include opportunities for viewpoints to be expressed from individuals in attendance who are not members of the panel. The NRC plans to transcribe the meetings.

DATES: Comments on this notice should be submitted by January 31, 2011. Comments

received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

Public Meeting Dates: The NRC will take public comments on the issues raised in this notice at a series of three 2-day public meetings that will be held during the weeks of October 25, 2010 (Washington, D.C.); November 1, 2010 (Los Angeles, California) and November 8, 2010 (Houston, Texas). The meeting in Washington DC will also include a third day of discussions, focused more specifically on the issues associated with power reactor licensees, as described in Section IV of this notice. Specific locations and dates will be announced on the NRC public website at <http://www.nrc.gov/public-involve/public-meetings/index.cfm>. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information.

ADDRESSES: Members of the public are invited and encouraged to submit comments by any of the following methods:

1. Mail to Cindy Bladey, Chief, Rules, Announcements and Directives Branch, Office of Administration, Mail Stop 5B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001;
2. Electronically at <http://www.regulations.gov>;
3. Electronically to Regs4RP@nrc.gov;
4. Electronically via the website dedicated to the potential changes to the NRC's radiation protection regulations at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/opt-revise.html>.
5. In person during one of the public meetings.

Comments will be made available to the public in their entirety. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against

including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this notice using the following methods:

Regulations.gov: Documents related to this notice, including public comments, are accessible at <http://www.regulations.gov>.

NRC's Public Document Room (PDR): The public may examine and have copied for a fee, publicly available documents at the NRC's PDR, Public File Area O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Document Access and Management System (ADAMS): Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Kimyata Morgan Butler, Office of Federal and State Materials and Environmental Management Programs, telephone (301) 415-0733, e-mail Kimyata.MorganButler@nrc.gov or Dr. Donald Cool, Office of Federal and State Materials and Environmental Management Programs, telephone (301) 415-6347, e-mail Donald.Cool@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Regulations issued by the U.S. Nuclear Regulatory Commission (NRC) are found in Chapter I of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR). Chapter I is divided into Parts 1 through 199, which contain requirements that are binding for all individuals and entities that possess, use, or store nuclear materials or operate nuclear facilities under the NRC's jurisdiction. Of these, the regulations that are most relevant to the subject of this notice are contained in 10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Part 50, "Domestic Licensing of Production, and Utilization Facilities." Through the existing compatibility criteria, the NRC Agreement States have certain requirements that are essentially identical to 10 CFR Part 20 for their licensees. Additional requirements, specific to particular uses or classes of facilities, are found in other portions of the regulations. For example, 10 CFR Part 35, "Medical Use of Byproduct Material," contains requirements related to medical use of radioactive material. Other portions of the regulations also may contain radiation protection criteria, and cross references to 10 CFR Part 20.

ICRP Publication 103 contains the latest in a series of revised international recommendations for radiation protection. Earlier recommendations of the ICRP concerning radiation protection were contained in ICRP Publication 2 (1959), ICRP Publication 26 (1977), and ICRP Publication 60 (1990). On December 18, 2008, the NRC staff provided a Policy Issue Notation Vote Paper (SECY-08-0197) to the Commission which presented the regulatory options of moving, or not moving, towards a greater degree of alignment between NRC's current radiation protection regulatory framework and the recommendations contained in ICRP Publication 103. In a Staff Requirements Memorandum (SRM) dated April 2, 2009, the Commission approved the staff's recommendation to immediately begin engagement with stakeholders and interested parties to ascertain the benefits, burdens, and potential stakeholder impacts if updates are made to NRC's radiation protection regulations and guidance in order to

achieve greater alignment with the recommendations in ICRP Publication 103. This notice and series of public meetings are part of the NRC staff's ongoing engagement process.

II. Request for Written and Electronic Comments and Plans for a Public Meeting

The NRC is soliciting comments on the technical issues and options, as presented in Sections III and IV of this notice. Comments may be submitted either in writing or electronically as indicated under the **ADDRESSES** heading. In addition, the NRC is holding a series of three public meetings, in the format of facilitated roundtable workshops, to be held during the weeks of October 25, 2010 (Washington, D.C.); November 1, 2010 (Los Angeles, California); and November 8, 2010 (Houston, Texas). Specific locations and dates will be announced on the NRC public website at <http://www.nrc.gov/public-involve/public-meetings/index.cfm>.

Sections III and IV provide background and topics of discussion on the major issues that will be the subject of the public meetings. During the public meetings, the NRC will conduct roundtable panel discussions, with a panel of participants, selected in a convening process to represent the diversity of stakeholders for these issues, including the various uses of radioactive materials licensed by the NRC. The meeting agenda will specifically include opportunities for viewpoints to be expressed from individuals in attendance who are not members of the panel. While all roundtable meetings will feature a discussion of technical issues and options for all types of licensed use of radioactive materials, as described in Section III of this notice, each meeting will have some degree of focus on particular types of licensed activity. The Washington, DC roundtable meeting will include a power reactor-focused session on the third day of the workshop, which will focus on issues described in Section IV of this notice. The roundtable meeting to be held in Los Angeles, California is intended to have additional medical use participation and the roundtable meeting held in Houston, Texas is intended to have additional industrial applications-focused (industrial radiography, well logging, etc.) participation. However, all interested stakeholders are encouraged to attend and participate in any of the

three workshops, including representatives from the university, research, manufacturer and distributors, and other sectors that use radioactive materials.

In addition to inviting public comments on the issues presented in Sections III and IV of this notice, the NRC is also requesting specific comments from potentially impacted industries. In Section III, the NRC is soliciting comments related to: (1) information on the projected costs and benefits resulting from consideration of the factors described in Sections III; (2) operational data on radiation exposures from various licensee groups; (3) whether the presented issues are addressed comprehensively; and (4) whether other options should be considered. In Section IV, the NRC is requesting comments from the nuclear power industry, and other stakeholders, specifically on operational considerations and costs and benefits to the industry increasing alignment of 10 CFR Part 50, Appendix I design objectives with the recommendations of ICRP Publication 103. The Commission believes that stakeholder comments will help to identify and quantify the potential impact of these proposed changes and will assist the NRC as potential regulatory action(s) are developed. Based on the comments received, the Commission will then be in a better position to evaluate whether to proceed with the development of a proposed rulemaking. If the Commission decides to proceed with a proposed rulemaking, additional information will be published in the *Federal Register* for public review and comment.

III. NRC Staff-Identified Technical Issues and Options Associated with the Potential Revision of NRC's Radiation Protection Regulations and Guidance

INTRODUCTION

Section A of the following discussion presents background information and describes some general considerations concerning potential revisions to NRC's radiation protection regulations, as identified by NRC staff. Section B discusses the various issues and options that need to be assessed before commencing regulatory activities related to initiating rulemaking to

change current radiation protection regulations. All public feedback will be used in developing an options paper for Commission consideration in late 2011.

A. Background

The Commission believes that the current NRC regulatory framework continues to provide adequate protection of health and safety of workers, the public, and the environment. From a safety regulation perspective, ICRP Publication 103 proposes measures that may be seen as going beyond what is needed to provide adequate protection. In order to ensure that the NRC is well informed of all the benefits and burdens associated with further alignment of NRC's current radiation protection regulations with ICRP Publication 103, the NRC is actively soliciting stakeholders' input to further clarify the issues, options, benefits, impacts, and/or burdens associated with making changes to the current NRC radiation protection regulations. These efforts include interactions with the public, the nuclear industry, the medical community, the radioactive materials community, States, and other Federal agencies (i.e., EPA, DOE, OSHA, etc.). The staff wishes to continue these interactions with more detailed stakeholder discussions during this series of facilitated roundtable workshops. The agenda for each workshop will feature the list of NRC staff-identified technical options and issues (described below) that are potential areas for revision of 10 CFR Part 20 in light of the recommendations contained in ICRP Publication 103. In addition, stakeholders and interested parties may introduce other options, issues, and information for the NRC's consideration.

The current NRC radiation protection framework, taken as a whole, is a collection based on three different generations of international radiation protection guidelines. 10 CFR Part 20 is based upon the 1977 recommendations contained in ICRP Publication 26, and the scientific information contained in ICRP Publication 30. In addition, 10 CFR Part 20 contains certain requirements based on recommendations and materials provided by the U.S. National Council on Radiation Protection and Measurements. Some other NRC requirements, including those for

10 CFR Part 50 Appendix I, are based on the older recommendations from 1959 contained in ICRP Publication 2. Certain licensees, as provided in specific license conditions, are implementing the more recent recommendations from 1990 in ICRP Publication 60 and subsequent publications updating the scientific information. The situation in other agencies of the Federal Government is similarly diverse, with requirements and guidance values based on all three previous generations of ICRP recommendations.

The recommendations in ICRP Publication 103 continue to be based on the fundamental principles of justification of exposures, optimization of protection, and limitation of dose. ICRP Publication 103 consolidates recommendations from ICRP Publication 60 and subsequent publications using a better integrated approach to radiation protection and in dealing with various types of radiation exposures. Among others things, exposures are divided into three fundamental exposure situations, planned exposure situations, existing exposure situations, and emergency exposure situations. Planned exposure situations include licensed activities where planning and controls are in place before the exposure is permitted. In each exposure situation, ICRP has placed an increased emphasis on the optimization of protection for such types of exposure situations. NRC regulations in 10 CFR Parts 20 and 50 are part of requirements in the United States for planned exposure situations, as described by the ICRP.

B. Issues and Options for Discussion

The following format is used in the presentation of the issues that follow. Each issue is assigned a number, a short title, regulatory options, and a list of questions. These issues, options, and questions are not meant to be a complete or final list, but are intended to initiate discussion. Interested stakeholders are welcome to recommend additions, deletions, or modifications of the key issues for consideration and propose implementation considerations. These issues and options will serve as the basis for discussion at the public meetings. Meeting

participants, and those wishing to make comments, are strongly encouraged to read more about this effort at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/opt-revise.html>.

Issue No. 1: Effective Dose and Numerical Values

Currently, 10 CFR Part 20 expresses the sum of internal and external exposures to an individual as the total effective dose equivalent (TEDE). In particular, the Commission amended the definitions in 10 CFR 20.1003 and 50.2 (72 FR 68058; 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). This action was made effective on February 15, 2008 (72 FR 72233; December 20, 2007). The revised definition of TEDE allows a licensee to substitute “effective dose equivalent” for “deep dose equivalent” (DDE) for external exposures, when calculated using a method found satisfactory to the Commission. Regulatory Guide 8.40 “Methods for Measuring Effective Dose Equivalent from External Exposure” recently updated and consolidated the guidance available on acceptable methods for calculation of effective dose. A conforming change was made to 10 CFR 20.1201(c) to clarify the determination of occupational radiation dose for adults. The rule change is consistent with the current recommendations of the ICRP.

The staff is considering whether it is appropriate to adopt current ICRP terminology and methodology throughout 10 CFR Part 20 and other portions of the regulations, by using the term TED instead of the term TEDE. ICRP publications no longer use the term TEDE or committed effective dose equivalent. The updated terminology has been associated with changes to various weighting factors within the calculation, but the underlying conceptual approach has remained the same.

Another area of consideration is changing the radiation protection weighting factors and numerical values. The weighting factors for tissues (W_T) and types of radiation (W_R) are currently specified in 10 CFR Part 20 in the definitions section, and are based on the

recommendations in ICRP Publication 26. ICRP Publication 103 recommendations provide new values for both quantities. Revising values for Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) is also an area of consideration. At this time, the ICRP is still in the process of developing a new set of dose coefficients, which will incorporate the revised radiation and tissue weighting factors and account for the latest biophysical models. The ICRP has indicated that the first volume of these new dose coefficients is expected in late 2011, although the publication of the complete set for occupational exposure and public exposure is not expected before 2014.

In considering Issue No. 1, the staff has identified two main issues and options that should be considered and discussed relative to effective dose and numerical values:

Issue No. 1.1: Clarifying effective dose methodology and assessing implications for licensee compliance with dose limits and changes to terminology

NRC staff wants to clarify, as stated above, that the revised definition of TEDE allows a licensee to substitute EDE for deep dose equivalent (DDE) for external exposures and that a conforming change was made to 10 CFR 20.1201(c) to clarify the determination of occupational radiation dose for adults. The issue of terminology goes beyond the simple introduction of a new term. Some of the NRC regulations continue to be based on older radiation protection approaches, and if these approaches are changed, then a question would be whether to make a change in the existing terminology of 10 CFR Part 20, or to the current terminology used worldwide. See Section IV for particular considerations in the power reactor community.

In consideration of the potential changes to terminology, the following three options should be considered:

- Options:
- 1.1a: No change in the current terminology (terminology remains TEDE)
 - 1.1b: Change the current regulation to align with the current ICRP Publication 103: Express as Total Effective Dose

1c: Allow use of either term

Questions: Q1.1-1: In terms of implementing the recently changed methodology for applying TEDE, are there any potential impacts on the ability to comply with the options for dose limits (DDE vs. TED)?

Q1.1-2: What are the anticipated impacts on records and reports?

Issue No. 1.2: Numerical Values and Weighting Factors

ICRP Publication 103 provided updated tissue and radiation weighting factors (W_T , W_R). In addition, the ICRP is in the process of revising the dose coefficients based on new values, models, and decay data. The weighting factors currently used in 10 CFR Part 20 date from 1977, and the corresponding ALI and DAC values are presented in 10 CFR Part 20 Appendix B. The NRC staff also notes that the EPA is currently examining the values presented in Federal Guidance Reports 11 and 13, and is considering an update of these values. The difference between the ICRP values and the EPA values stems primarily from the use of a U.S. population cancer incidence and mortality analysis, instead of an average set of cancer incidence and mortality values for a worldwide population. In discussion with stakeholders to date, the majority have been generally in favor of updating the scientific information. However, no specific information related to potential impacts has been presented.

The following are options and questions are related to this issue:

Options: 1.2a: No change

1.2b: Change the current regulation to align with the current ICRP Publication

103: Update to new values, models, and radionuclide decay data

Questions: Q1.2-1: Are there any foreseen impacts of the timing (2014) of making changes to the current numerical values and weighting factors? Should NRC consider moving forward with a more limited set of radionuclides that would

be available more quickly, and make subsequent amendments to add additional values as they are published by the ICRP?

Q1.2-2: Should the NRC use the values developed by the EPA, which will be based on a US population, instead of the ICRP values, which are based on a more diverse world population?

Issue No. 2: Occupational Dose Limits

The occupational dose limit of 10 rem (100 mSv) over 5 years, with a maximum of 5 rem (50 mSv) in any one year, recommended by ICRP in 1990, was not incorporated into the last revision of 10 CFR Part 20 because the recommendations were not available during the public comment period for the proposed rule. The ICRP recommendations have now been adopted, in some form, by the International Atomic Energy Agency in their International Basic Safety Standards (BSS), and by most of the other countries in the world. In some countries, the limits are as recommended by the ICRP. In other cases, the national authorities have chosen to require a single 2 rem (20 mSv) limit for occupational exposure. In the discussions with stakeholders that have already taken place, the occupational dose limits issue has also included discussion of the relationship between the limits, and any proposal related to establishing constraints for occupational exposure (see Issue No. 4).

The NRC staff is aware from stakeholder interactions that there are significant global or trans-boundary considerations that are important to some licensees which would argue in favor of changes in the dose limits. The staff is also aware that many other licensees wish to leave the current NRC regulations as they are. Factors identified have included potential impacts to licensees who have occupationally exposed individuals who are currently receiving exposures in excess of 2 rem (20 mSv) in a year.

The NRC staff has identified the following three options for changes to NRC's occupational dose limits:

- Options: 2.a: No change. Allow the dose limit to remain at 5 rem (50 mSv) per year.
- 2.b: Change the current regulation to align with the current ICRP Publication 103: 10 rem (100 mSv) over 5 years, with a maximum of 5 rem (50 mSv) in any one year.
- 2.c: Change the current regulation to align with the approach adopted by some other countries: yearly dose limit of 2 rem (20 mSv).

- Questions: Q2-1: Are there any significant anticipated impacts in assessing and retaining dose histories for each individual in order to comply with a multi-year average?
- Q2-2: Are there any anticipated implementation impacts expected if the dose limit is decreased?
- Q2-3: Is there any information about the actual dose distributions for industrial and medical licensees? What are the trends for this data? Are the data available to share with the NRC?
- Q2-4: For the medical industry, are there any potential impacts on patient care?

Issue No. 3: Doses to Special Populations

Issue No. 3.1: Dose Limits for embryo/fetus of a declared pregnant worker

The limits for the embryo/fetus of a declared pregnant worker are specified in 10 CFR 20.1208. Currently, the dose limit to the embryo/fetus of a declared pregnant worker is 0.5 rem (5 mSv) for the gestation period with 0.05 rem (0.5mSv) additional dose during the gestation period if the dose to the embryo/fetus has already exceeded 0.5 rem (5 mSv) at the time of declaration. The current requirements are based on the recommendations available in ICRP Publication 26. The ICRP recommendations now state that protection should be provided that

is generally equivalent to that provided to a member of the public. Thus, the ICRP has now recommended a simplified approach, which is 100 mrem (1 mSv) after the declaration of pregnancy.

In the discussions with stakeholders that have already taken place, many stakeholders have indicated that the ICRP proposal would not cause any issues. However, the NRC staff is also aware of some licensee segments, such as Nuclear Pharmacy licensees, where the change could result in an impact. To date, specific information and supporting data on impacts has not been received.

The NRC staff identified the following three options for the dose limit to an embryo/fetus of a declared pregnant worker:

- Options:
- 3.a: No change. Continue with the dose limit of 0.5 rem (5 mSv) per year.
 - 3.b: Change the current regulation to align with the current ICRP Publication 103: 100 mrem (1 mSv) after the declaration of pregnancy.
 - 3.c: Change the current regulation to another single value after declaration: For example, 0.05 rem (.5 mSv) after declaration, the provision of the current rule if a dose of 0.5 rem (5 mSv) has already been exceeded at the time of declaration of the pregnancy.

- Questions:
- Q3-1: Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts?
 - Q3-2: Are there any anticipated implementation impacts on record keeping?
 - Q3-3: Is there a reduction in burden in assessment and record keeping if the ICRP recommendation is considered for adoption?
 - Q3-4: Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP recommendation difficult in certain circumstances?

Q3-5: Is there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for this data? Is this data available to share with the NRC?

Issue No. 3.2: Dose Limits for members of the public, alternative provisions for 500 mrem (5 mSv)

In addition to the dose to the embryo/fetus of a declared pregnant female, stakeholders have asked about the implementation of the ICRP recommendations to sensitive populations. In particular, stakeholders have noted that the ICRP recommendations have stated that, although the dose limits for members of the public continue to provide flexibility for doses greater than 100 mrem (1 mSv) in certain limited circumstances, sensitive populations such as young children should not be allowed to receive doses greater than the dose limits. This leads to an issue regarding the public dose limits that the NRC staff has not previously solicited comments.

The current NRC public dose limits in 10 CFR 20.1301 contain a provision that allows for licensees to apply for a limited application of a dose limit up to 500 mrem (5 mSv). In consideration of the ICRP's latest set of recommendations, the following options have been identified:

- Options:
- 3.2-a: No change. Continue to allow a dose limit of 0.5 rem (5 mSv) per year, applicable only upon specific approval of a licensee request.
 - 3.2-b: Change the current regulation to limit the applicability of the provision to situations in which sensitive populations are not receiving the exposure.
 - 3.2-c: Clarify in guidance that the NRC will require licensees to demonstrate that sensitive populations are not included in any proposals for alternative public dose limits.

Questions: Q3.2-1: Are there any significant anticipated impacts associated with limiting the applicability of alternative public dose limits?

Q3.2-2: Are these impacts the same for the options of a rule change, or for changes to guidance?

Q3.2-3: Is there data available about the actual use of the alternative dose criteria? Is this data available to share with the NRC?

Issue No. 4: Incorporation of Dose Constraints

One of the most significant recommendations made in ICRP Publication 103 was the increased emphasis on the use of constraints and reference levels as part of the process of optimization of protection for all exposure situations. Licensees are currently required by 10 CFR 20.1101 to use sound radiation protection principles to achieve occupational doses and doses to members of the public that are 'As Low As Is Reasonably Achievable (ALARA). The term, "constraint," is already included in the definitions of 10 CFR Part 20. A constraint, as currently defined, is a value at which licensee actions are required. Many licensees are generally familiar with the concept of constraints, although the term may be unfamiliar, because the concept is very similar to the use of various types of planning values (such as self-imposed administrative limits) in their programs to ensure that the dose limits are not exceeded. Thus, many established radiation protection programs already incorporate this concept, at least to some degree. The ICRP recommendations indicate that the constraint is the starting point for optimization, serving as an upper bound on the annual dose for members of the public, or an occupationally exposed individual, should receive from the planned operation of any controlled source of radiation. ICRP has stated that constraints are not to be considered as limits. In the discussions with stakeholders that have already taken place, many stakeholders have asked questions about the concept of constraints, the relationship of constraints to limits, and the relationship between possible changes to the limits and the use of constraints. In the current

NRC regulatory structure, a constraint is defined as a level at which a licensee action is required. This provision is applied to airborne effluents from non-reactor facilities, and the actions are to evaluate the situation, develop actions to return effluents levels to less than the constraint, and provide a report to the NRC. Thus, as presently used in the regulations, an effluent release in excess of the numerical value of the constraint is not a violation. A violation only occurs if actions are not implemented in response to the situation. This approach is similar to the description presented by the ICRP, where a dose in excess of the constraint would not be seen as a violation, but as a point when reevaluation of the planning and implementation of the optimization ALARA program is needed.

A number of stakeholders have expressed an interest in exploring the implications of using the mandatory application of constraints as a mechanism to achieve the same level of protection as a change in dose limits, while retaining some flexibility on the part of the licensee to examine and control their own programs. The NRC staff is interested in continuing to explore these proposals and their implications from various groups of licensees.

NRC staff has identified three options for the incorporation of dose constraints to NRC's radiation protection framework:

- Options:
- 4.a: No change. Do not incorporate the use of constraints into NRC's radiation protection framework.
 - 4.b: Change the current regulation to specify that licensees establish and use constraints as part of their radiation protection program and the implementation of the ALARA requirement.
 - 4.c: In addition to requiring the establishment and use of constraints, require that the licensee use a numeric value that does not exceed some specified value. One such value for occupational exposure could be the 2 rem (20 mSv) per year level.

Questions: Q4-1: Are there any significant anticipated benefits and impacts associated with imposing the use of constraints in a licensee's radiation protection program?

Q4-2: Are there any anticipated implementation impacts on inspection, compliance, and reporting anticipated?

Q4-3: What relationship should a constraint have to the dose limit, if any?

Q4-4: Is a requirement to establish and use constraints an appropriate, or inappropriate, insertion of a regulatory requirement?

Q4-5: How familiar are you with the use and implementation of constraints or planning values in a radiation protection program?

Q4-6: Are constraints (planning values) used in your current licensed activities, and if so, can you share insights on the use of these constraints?

IV. NRC Staff-Identified Technical Issues and Options Associated with the Possible Revision of 10 CFR Part 50, Appendix I Regulations and Guidance

Section A of the following discussion presents background information and describes general considerations concerning potential revisions to NRC regulations controlling radioactive liquid and gaseous effluent releases in the environment, as identified by NRC staff. The regulations are contained in Appendix I to 10 CFR Part 50, "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." Section B discusses the various issues and options that need to be assessed before initiating any regulatory activities leading to a rulemaking proposing to align the dosimetry basis, current dose terminology, and dose calculation methods of 10 CFR Part 50, Appendix I design objectives with the recommendations of ICRP Publication 103.

A. Background

In 1975, the NRC adopted the ALARA principle in regulating radioactive liquid and gaseous effluent releases from nuclear power plants. Radioactive liquid and gaseous effluents are controlled under 10 CFR Part 20, 10 CFR Parts 50.34a and 50.36a, and Appendix I to 10 CFR Part 50. 10 CFR Part 50, Appendix I contains provisions to ensure that gaseous and liquid radioactive effluents released in unrestricted areas and doses to members of the public are ALARA. These requirements are based on dosimetry concepts issued in 1959 as ICRP Publication 2. This approach was consistent with the version of Part 20 in effect prior to 1991, but is no longer consistent with current 10 CFR Part 20.

The revision under consideration may propose the adoption of the radiation protection framework recommended by ICRP Publication 103. This NRC staff is considering the approach in parallel with the consideration of changes to 10 CFR Part 20 so that the resulting requirements can be consistent.

The Commission believes that the current NRC regulatory framework of 10 CFR Part 50, Appendix I, and reactor oversight program continues to ensure that gaseous and liquid radioactive effluents released in unrestricted areas and doses to members of the public are ALARA. The alignment of 10 CFR Part 50, Appendix I regulations and design objectives with ICRP Publication 103 recommendations would not be intended to change the design objective criteria and regulatory guidance used by the nuclear power industry in demonstrating compliance with these requirements.

B. Issues and Options for Discussion

Issue No. 1: Proposed Revision to the Basis of 10 CFR Part 50, Appendix I Design

Objectives

Currently, the design objectives of 10 CFR Part 50, Appendix I, and associated guidance documents, are still based on ICRP Publication 2 dosimetry concepts, which include dose to the whole body and to critical organs. The ICRP Publication 26 and ICRP Publication 103

recommendations moved to a more risk-based approach, and expressed the dose limits as TEDE, a sum of external and internal radiation exposures. Currently, nuclear power plant licensees must apply two different methodologies in calculating doses, one in determining compliance with the requirements of 10 CFR Part 50, Appendix I, and another in calculating doses to members of the public under 10 CFR Part 20. The intent of a possible revision is to align and improve 10 CFR Part 50, Appendix I regulations and guidance 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, and promulgation of 10 CFR Part 50 and Appendix I in 1975.

The staff has identified three main issues and options that should be considered and discussed relative to alignment with more recent recommendation:

Options: 1.a: Leave the basis of 10 CFR Part 50, Appendix I design objectives as is and continue to apply the requirement under existing NRC guidance and industry practices. This approach argues that there is no necessary connection between 10 CFR Part 50, Appendix I design objectives and 10 CFR Part 20 dose limits to the public, given that 10 CFR Part 50, Appendix I is not a radiation protection standard under 10 CFR Parts 50.34a. The 10 CFR Part 50, Appendix I design objectives are an “ALARA design basis” requirement. If the numerical guides for design objectives and ALARA provisions of 10 CFR Part 50, Appendix I are met, it constitutes a demonstration that effluent releases and associated doses to the public are ALARA and no additional efforts are required to reduce radioactive effluent releases. As a result, it could be argued that there is no need to link the two. This approach would result in minor revisions to supporting NRC guidance. The revision would require that a few regulatory guides, currently as draft, be finalized and re-issued as final.

1.b: Align dose definitions and quantities of 10 CFR Part 50, Appendix I criteria with the ICPR 103 recommendations, in parallel with any changes made to 10 CFR Part 20. This approach argues that there is a benefit in aligning the basis of 10 CFR Part 50, Appendix I design objectives with 10 CFR Part 20, as updated to ICRP Publication 103 recommendations. This approach would ensure a consistent application of regulatory criteria between 10 CFR Part 20 and 10 CFR Part 50. Such a revision could offer the opportunity to standardize the process to a common regulatory basis in calculating doses. This approach would result in significant revisions to

supporting NRC guidance, including key regulatory guides, NUREG documents, and computer codes.

1.c: Align dose definitions and quantities of 10 CFR Part 50, Appendix I design objectives with the current framework of 10 CFR Part 20 based on ICRP Publication 26. This approach has the same goal as option 1.2, and is offered as an option if the NRC decides to not update 10 CFR Part 20. As before, this approach would ensure a consistent application of regulatory criteria between 10 CFR Part 20 and 10 CFR Part 50. The revision would result in standardization to a common but still outdated regulatory dosimetry basis and method in calculating doses. This approach would result in significant revisions to supporting NRC guidance, including key regulatory guides, regulatory guides (NUREG) documents, and computer codes.

Questions: Q1-1: What are the benefits and impacts of each option identified above? Is there a preferred ranking of the options?

Q1-2: What is the scope of operational impacts and costs in updating programs and procedures given a revision of 10 CFR Part 50, Appendix I design objectives and NRC guidance? Identify specific types of impacts that the NRC should consider in implementing a revision of 10 CFR Part 50, Appendix I design objectives and NRC guidance to ICRP Publication 103 recommendations.

Q1-3: Are there estimates available for the costs to revise operational programs, implementing procedures, computer codes, and personnel training for a typical pressurized water reactor (PWR) and boiling water reactor (BWR) power plant or for a generic power plant? Is there an estimate of the aggregate cost for the operating fleet of nuclear power reactors?

Q1-4: Should the NRC combine both 10 CFR Part 20 and 10 CFR Part 50, Appendix I updates into one rulemaking effort, or consider two parallel rulemaking efforts with the implementation of the revised rules synchronized to a common implementation date when all regulatory conforming changes and revisions of implementing guidance are completed for 10 CFR Part 20 and 10 CFR Part 50, Appendix I?

Issue No. 2: Voluntary or required implementation of revised 10 CFR Part 50, Appendix I regulations

This issue examines the different possibilities for implementation of a possible revision for existing licensee facilities. Voluntary implementation should not pose any backfitting considerations under the Backfit Rule (10 CFR 50.109). However, the staff would need to address the potential impacts on the reactor inspection program for those plants and new applicants that would voluntarily implement the revised regulations.

Options: 2.a: No change. Leave the current requirements and guidance intact for all currently licensed and operating plants under Parts 50 and 52.

2.b. Make the implementation of new requirements voluntary for all currently licensed and operating plants under Parts 50 and 52 using a separate set of revised 10 CFR Part 50, Appendix I regulations and guidance.

2.c. Require the implementation of revised 10 CFR Part 50, Appendix I regulations and guidance for all operating plants and applicants over time with a mandated common implementation date.

Questions: Q2-1: If 10 CFR Part 50, Appendix I was revised, should the NRC make the implementation of the revised requirements voluntary or mandatory on all nuclear power plant licensees?

Q2-2: If 10 CFR Part 50, Appendix I were revised and became mandatory, what should be the duration of the implementation phase for power plant licensees, e.g., 2, 4, or 6 years?

Issue No. 3: Approaches and Considerations in Revising 10 CFR Part 50, Appendix Regulations

In addition to the possible update of dosimetric concepts and methods, there are a number of additional areas within 10 CFR Part 50 Appendix I which could be considered for possible revision and update. The staff is examining a tiered set of options, reflecting increasing levels of complexity of the update, with the scope of the revision ultimately depending on the chosen option on how to proceed with the revisions, whether the implementation is mandated or voluntary, and taking full considerations of impacts on regulations and guidance.

Options: 3.a: Limited Scope Revision – Besides specific revisions to the regulations, target only those elements of the guidance dealing with dose conversion factors and, if necessary, directly supporting radiological parameters, such as specific adjustments to the basis of dose conversion factors, based on ICRP Publication 103 or ICRP Publications 26 and 30. The balance of the technical guidance and default values of other parameters would remain as stated in current regulatory guides. The revision would identify changes to computer codes using new dose conversion factors based on ICPR Publication 103 or ICRP Publications 26 and 30 recommendations.

3.b: Expanded Scope Revision - In addition to the above, the basis of specific parameters used in dose calculations would be evaluated, and an assessment would identify the need to update or retain specific default values. Such parameters, for example, would include human food or animal consumption rates, bio-accumulation factors, shore-line width factors,

agricultural productivity rates, usage and time factors for exposed individuals, etc. The revision would also identify changes to computer codes using new dose conversion factors based on ICPR Publication 103 or ICRP Publications 26 and 30 recommendations.

3.c: Full Scope Revision - This approach would consider a full review of the guidance, including a complete update of models addressing liquid and gaseous treatment options and development of radiological effluent source terms, atmospheric and aquatic dispersion, and environmental transport using the current literature and industry standards. The review would assess model assumptions, parameters (as partly described above), and their default values. The revision would identify changes to computer codes, modeling assumptions and parameters, and apply new dose conversion factors based on ICPR Publication 103 or ICRP Publications 26 and 30 recommendations.

Questions: Q3-1: Which option should the NRC apply in aligning 10 CFR Part 50, Appendix I regulations with ICRP Publication 103 if 10 CFR Part 20 were revised, or with ICRP Publications 26 and 30 if 10 CFR Part 20 were not revised?

Q3-2: What are the impacts and benefits in the implementation of revised 10 CFR Part 50, Appendix I regulations that the NRC should consider?

Q3-3: If significant impacts in the implementation of revised 10 CFR Part 50, Appendix I regulations are envisioned, what types of issues should the NRC evaluate and consider in revising 10 CFR Part 50, Appendix I regulations?

Issue No. 4: Scope of Revisions to 10 CFR Part 50, Appendix I Regulations

At this time, the NRC assumes that any proposed revision to 10 CFR Part 50, Appendix I will be multi-fold. One aspect involves conforming changes in ensuring that the nomenclature

used in defining doses and dosimetric quantities, as described in Issue 1 above. The implementation of conforming changes in regulations and guidance is expected to be a relatively simple process, once all nomenclatures and definitions have been finalized and integrated in a revised 10 CFR Part 20. However, some challenges are expected in modifying some of the regulatory provisions of Appendix I to 10 CFR Part 50. The following identifies specific provisions of Appendix I to 10 CFR Part 50 and 10 CFR Part 20 regulations that may need to be reviewed and updated, as warranted:

Provisions: 4.1: Numerical design objectives of 10 CFR Part 50, Appendix I for liquid and gaseous effluents - The revision would retain the current numerical dose criteria, but would redefine doses as effective dose (ED) or TED for consistency with ICRP Publication 103 dosimetry concepts in a revised 10 CFR Part 20, or as TEDE with the current 10 CFR Part 20 (ICRP Publications 26 and 30) if 10 CFR Part 20 were not realigned with ICRP Publication 103. The update would necessitate a revision of dose calculation methods described in Regulatory Guide 1.109 and associated computer codes.

4.2: Organ numerical design objectives of 10 CFR Part 50, Appendix I for liquid and gaseous effluents - The revision would assess whether there is still a need to report doses separately for organs since this would not be necessary if ICRP Publication 103 or ICRP Publications 26 and 30 were adopted. The assessment would consider the provisions of Sections II and III of Appendix I to 10 CFR Part 50 on doses associated with radioiodine in situations where releases might be dominated by the presence of noble gases and radioiodine, resulting in potentially significant skin and thyroid doses. The assessment would also consider the need to revise the scope of thyroid dose contributors to include radionuclides present as vapor

(tritium) and gases (e.g., ^{14}C in inorganic and organic forms) in addition to radioiodine and particulates.

4.3: Annual gamma and beta air dose for gaseous effluents - The gamma and beta dose criteria characterize an absorbed dose rate in air, expressed in mrad/year, while the balance of the design objectives are expressed in mrem/year for the total body and organs. The revision would assess the need to still report gamma and beta absorbed air dose results based on a review of historical gaseous effluent releases and doses from operating PWR and BWR plants. The revision might consider dropping that requirement altogether, or alternatively, converting the design objective to an ED or TED dose for a receptor assumed to be located at the site boundary.

4.4: Light-Water-Cooled Reactor Provisions of Appendix I to 10 CFR Part 50 - The revision would consider whether there is a need to expand current regulatory provisions for design certifications and new reactor applications involving other types of reactor technologies. Such new technologies might include new types of reactor fuels and modular reactor technologies, e.g., high temperature gas-cooled reactors, molten-salt or lead-cooled reactors, and breeder reactors.

4.5: Compliance with Requirements for “Licensed Operation” under 10 CFR Part 20 - The revision would consider the need to expand provisions describing compliance requirements for “licensed operation” for sites with two or more licensed entities contributing to and radiation exposures to a single offsite dose receptor under Parts 20.1301(a)(1) and 20.1302(a) and (b). The expanded provisions would identify acceptable methods in the regulation or guidance for apportioning radioactive effluent

releases and doses between two or more licensed entities. The discussion would also consider compliance with EPA regulations of 40 CFR Part 190 as implemented under 10 CFR Part 20.1301(e).

Questions: Q4-1: Given the above summary descriptions of the provisions of 10 CFR Part 50, Appendix I that might be considered for possible revision, should the NRC evaluate all provisions described above, or focus instead only on those necessary to align 10 CFR Part 50, Appendix I regulations with ICRP Publication 103 if 10 CFR Part 20 were revised, or with ICRP Publication 26 and 30 if 10 CFR Part 20 were not revised?

Q4-2: Given the above, are there any significant impacts in the implementation of revised 10 CFR Part 50, Appendix I regulations that the NRC should consider if it were to proceed with a rulemaking?

Q4-3: If significant impacts in the implementation of revised 10 CFR Part 50, Appendix I regulations are envisioned, what types of issues

should the NRC evaluate and consider in revising 10 CFR Part 50,
Appendix I regulations.

Dated at Rockville, Maryland, this 20th day of September, 2010.

For the Nuclear Regulatory Commission.

/RA/

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