



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[NRC-2009-0279]

RIN 3150-AJ29

Radiation Protection

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing this advance notice of proposed rulemaking (ANPR) to obtain input from stakeholders on the development of a draft regulatory basis. The draft regulatory basis would support potential changes to the NRC's current radiation protection regulations. The goal of this effort is to achieve greater alignment between the NRC's radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007). Through this ANPR, the NRC has identified specific questions and issues with respect to a possible revision of the NRC's radiation protection requirements. Stakeholder comments, including responses to the specific questions, will be considered by the NRC staff when it develops the draft regulatory basis. In a separate and related activity, the NRC staff will be preparing an ANPR concerning the NRC's design objectives governing dose assessments for radioactive effluents from light-water-cooled nuclear power reactors, which should be published for public comment during the public comment period for this ANPR. The NRC plans to hold a

series of public meetings to promote full understanding of the contemplated action and facilitate public comment.

DATES: Submit comments by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration of comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2009-0279. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Cardelia Maupin, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2312; e-mail: Cardelia.Maupin@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments.

A. Obtaining Information.

Please refer to Docket ID NRC-2009-0279 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2009-0279.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):**
You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in

the SUPPLEMENTARY INFORMATION section. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

- **NRC’s PDR:** You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments.

Please include Docket ID NRC-2009-0279 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background.

The NRC's primary radiation protection regulations are in part 20 of Title 10 of the *Code of Federal Regulations* (10 CFR). The purpose of these regulations is to establish standards of protection for both members of the public and occupational workers from ionizing radiation resulting from activities conducted under licenses issued by the NRC. These standards are implemented through the radiation protection requirements in the 10 CFR part 20 regulations that NRC licensees must follow. The NRC's predecessor agency, the Atomic Energy Commission (AEC), initially issued its regulations for radiation protection in the *Federal Register* (FR) on January 29, 1957 (22 FR 548). The regulations substantially followed the recommendations of the first official publication of the then National Committee on Radiation Protection and Measurement, which was renamed in 1964 when it was officially chartered by the U.S. Congress (Public Law 88-376) and is now known as the National Council on Radiation Protection and Measurements (NCRP). The NCRP report was published in 1953 by the Subcommittee on Permissible Internal Dose, *Handbook 52*, "Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water" (NCRP 1953).¹ The ICRP essentially adopted the NCRP 1953 recommendations in "Recommendations of the International Commission on Radiological Protection," December 1, 1954," except for one major deviation. The ICRP was the first to recommend limiting radiation doses to persons other than radiation workers, that is, to members of the

¹ "A Review of the History of U.S. Radiation Protection Regulations, Recommendations, and Standards," by C.G. Jones, *Health Physics Journal*, February 2005, Vol. 88, No. 2, pages 105-126 (ADAMS Accession No. ML050400427), "1956 Report on Amendments during 1956 to the 1954 Recommendations of the International Commission on Radiological Protection," 1956, ICRP, and "Maximum Permissible Radiation Exposure to Man, A preliminary statement of the National Committee on Radiation Protection and Measurements," 1957.

public. It recommended a dose one tenth of that acceptable for occupational workers, which the NCRP later adopted in 1958.²

Throughout the mid to late 1950s, the ICRP and the NCRP adopted similar recommendations. For example, in April 1956, the ICRP considered changes to its dosimetry system that included recommendations for accumulated internal dose limits for the critical organs of the human body. The ICRP issued a recommendation of 50 mSv (5 rem) per year for the whole body, gonads, lens of the eye, and active bone marrow of occupational workers. This recommendation was later adopted by both the NCRP and the ICRP (NCRP 1957 and ICRP 1958).³ The AEC's 1957 final rule that promulgated 10 CFR part 20, and the 1960 amendments to 10 CFR part 20 (25 FR 8595, September 7, 1960; and 25 FR 10914, November 17, 1960), reflect collaborative efforts between the ICRP and NCRP. Therefore, the dose calculation methodology for the AEC's radiation protection standards was based, in part, upon the compilation of the ICRP recommendations developed during the mid to late 1950s and contained in ICRP Publication 1, "Recommendations of the International Commission on Radiological Protection," 1959; and ICRP Publication 2, "Permissible dose for internal radiation," 1959.

Following the establishment of the NRC in 1975, the next and last revision of 10 CFR part 20 was published in the *Federal Register* on May 21, 1991 (56 FR 23360). The purpose of the 1991 revision was to adopt the basic tenets of the ICRP system of radiation dose limitation described in ICRP Publication 26 (1977), "Recommendations of the ICRP."⁴ The 1977 recommendations significantly modified previous radiation protection concepts and principles.

² "1954 Recommendations of the International Commission on Radiological Protection," 1955, and "Permissible Dose: A History of Radiation Protection in the Twentieth Century," by Samuel Walker, 2000, page 12.

³ The recommended ICRP reference format is: "Recommendations of the International Commission on Radiological Protection, ICRP Publication 1 (1959)," and the condensed reference format used in this document is: ICRP Publication 1 (1959).

⁴ The recommended ICRP reference format is: "ICRP, 1977. Recommendations of the ICRP. ICRP Publication 26. Ann. ICRP 1 (3)," and the condensed reference format used in this document is: ICRP Publication 26 (1977).

It established a new risk-based system of radiation protection based on three principles: justification, optimization, and limitation. (1) Justification requires that no new practice or operation involving radiation should be allowed unless it produces a net benefit (i.e., no frivolous use of radiation). (2) Optimization requires all exposures to be kept as low as is reasonably achievable (ALARA) taking into account all relevant social and economic factors. (3) Limitation requires that the effective dose equivalent to individuals shall not exceed the limits (dose limits) as established for appropriate circumstances. The ICRP Publication 26 (1977) also provided for the summation of internal and external exposures for the first time, and eliminated the concept of a threshold effect or tolerance dose and introduced the concept of carcinogenesis as a stochastic effect (i.e., health effects that occur randomly). It provided the foundation and basis for all current Federal and State regulations, except the U.S. Department of Labor's, which is still based upon the ICRP recommendations of the 1950s. (Reference: "A Review of the History of U.S. Radiation Protection Regulations, Recommendations, and Standards," by C.G. Jones, *Health Physics Journal*, February 2005, Vol. 88, No. 2, page 113, (ADAMS Accession No. ML050400427), and *Radiation Protection*, Chapter 4, page 4-3, by J.U. Burnham, et al, 1992)

The majority of the ICRP Publication 26 (1977) recommendations were adopted in NCRP Report No. 91 (1987), "Recommendations on Limits for Exposure to Ionizing Radiation." The 1987 report replaced NCRP Report 39 (1971), "Basic Radiation Protection Criteria," and NCRP Report No. 43 (1975), "Review of the Current Status of Radiation Protection Philosophy." Therefore, the majority of the NCRP Report No. 91 (1987) recommendations were adopted in the 10 CFR part 20 amendments of 1991. The NCRP recommendations were issued after the publication of the proposed 10 CFR part 20 rule; as a result, some of its recommendations were not adopted in the final rule. For more information about ICRP Publication 26 (1977) and NCRP Report No. 91 (1987) recommendations incorporated into 10 CFR part 20 final rule, please see

the statement of considerations for the 1986 proposed 10 CFR part 20 rule (51 FR 1092) and the 1991 final 10 CFR part 20 rule (56 FR 23391).

The 1991 revisions to 10 CFR part 20 were also supported by information in ICRP Publication 30 (1979-1988), "Limits for Intakes of Radionuclides by Workers,"⁵ including its four parts, four supplements and index, which were published during the period of 1979 through 1988; and ICRP Publication 32 (1981), "Limits for Inhalation of Radon Daughters by Workers." These documents were used to calculate the inhalation values for the annual limits on intake (ALIs) and derived air concentrations (DACs) for the radionuclides in 10 CFR part 20, appendix B. For more information about the application of these ICRP publications to the 10 CFR part 20 amendments, please see the statement of considerations for the 1986 proposed 10 CFR part 20 rule (51 FR 1092, 1121) and the 1991 final 10 CFR part 20 rule (56 FR 23391).

In ICRP Publication 45 (1985),⁶ ICRP issued a statement recommending that the annual dose limit for members of the general public be reduced from 5 mSv (500 mrem) to 1 mSv (100 mrem); this annual dose limit which was adopted in the NRC's 1991 rulemaking.⁷ In addition, when the 10 CFR part 20 rulemaking was near completion, the ICRP developed a new series of recommendations as ICRP Publication 60 (1991).⁸

⁵ ICRP Publication 30 was published in four parts and several supplements. These publications are: "ICRP, 1979. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 1). Ann. ICRP 2 (3-4);" "ICRP, 1979. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Supplement to Part 1). Ann. ICRP 3 (1-4);" "ICRP, 1980. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 2). Ann. ICRP 4 (3-4);" "ICRP, 1981. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Part 3). Ann. ICRP 6 (2-3);" "ICRP, 1982. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Supplement B to Part 3). Ann. ICRP 8 (1-3);" "ICRP, 1982. Limits for Intakes of Radionuclides by Workers. ICRP Publication 30 (Index). Ann. ICRP 8 (4);" and "ICRP, 1988. Limits for Intakes of Radionuclides by Workers: An Addendum. ICRP Publication 30 (Part 4). Ann. ICRP 19 (4)." These publications are referenced collectively in the condensed reference formats as ICRP Publication 30 (1979-1988).

⁶ The recommended ICRP reference format is: ICRP, 1985. Developing a Unified Index of Harm. ICRP Publication 45. Ann. ICRP 15 (3), and the condensed reference format used in this document is: ICRP Publication 45 (1985).

⁷ International Commission on Radiological Protection, "Statement from the 1985 Paris Meeting of the ICRP," *British Journal of Radiology*, Vol. 58, page 910:1985; also; *Health Physics*, 45(6), pages 828-829 (June 1985).

⁸ The ICRP recommended format is: ICRP, 1991. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1-3), and the condensed reference format used in this ANPR is: ICRP Publication 60 (1991).

The ICRP Publication 60 (1991) recommendations included lowering the occupational dose⁹ limit from 50 mSv (5 rem) per year to a 5-year average of 20 mSv (2 rem) per year, with the dose in any given year not to exceed 50 mSv (5 rem); eliminating dose limits for individual organs, except for the skin and the lens of the eye; lowering the exposure limits to an embryo/fetus during the gestation period from 5 mSv (500 mrem) to 4.5 mSv (450 mrem); and changing radiation protection terminology and definitions. The ICRP Publication 60 (1991) recommendations were not considered in the NRC's 1991 rulemaking because they were issued after the rule's public comment period ended. Following the issuance of ICRP Publication 60 (1991), the ICRP issued a series of publications that revised internal dosimetry models. The revised internal dosimetry models superseded many, but not all, of the models described in ICRP Publication 30 (1979-1988) and earlier ICRP publications. As a result, there are differences between 10 CFR part 20 and the dosimetry approaches and occupational dose limits reflected in ICRP Publications 60-61, 66-69, 71-72, and 74.¹⁰

Other than conforming changes to update cross-references to 10 CFR part 20 found in other NRC regulations, the 1991 rulemaking did not substantively revise other NRC regulations (e.g., 10 CFR parts 32, 50, 51, 61, and 72) that had explicit dose criteria. Consequently, some NRC regulations are still based on ICRP Publication 1 (1959), ICRP Publication 2 (1959), and

⁹ The NRC's regulations define "occupational dose" as "the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public." 10 CFR 20.1003 (definition of "occupational dose").

¹⁰ ICRP Publication 61 (1991), "Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations;" ICRP Publication 66 (1994), "Human Respiratory Tract Model for Radiological Protection;" ICRP Publication 67(1993), "Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients;" ICRP Publication 68 (1994), "Dose Coefficients for Intakes of Radionuclides by Workers;" ICRP Publication 69 (1995), "Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 3 Ingestion Dose Coefficients;" ICRP Publication 71 (1995), "Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients;" ICRP Publication 72 (1995), "Age-dependent Doses to the Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients;" and ICRP Publication 74 (1996), "Conversion Coefficients for use in Radiological Protection against External Radiation."

NCRP reports of the 1950s. The differences between the 10 CFR part 20 requirements and the ICRP recommendations issued after ICRP Publication 30 (1979-1988) have created challenges for the NRC and its licensees.

The NRC staff described these challenges in its paper to the Commission, 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," dated August 2, 2001 (ADAMS Accession No. ML011580363). Specifically, the challenges included licensee requests to use dosimetry methods based upon the recommendations in the various ICRP publications issued after ICRP Publication 30 (1979-1988) for both external (to the body) and internal (within the body) dose assessments; licensees exceeding, or potentially exceeding, dose limits, although the NRC staff had determined that in some cases the 10 CFR part 20 methods for assessing internal and external dose were overly conservative relative to the most current ICRP recommendations; the general areas of differences between radiation protection requirements of the NRC and those nations that relied upon the later ICRP recommendations, including the differences in occupational exposure limits; and the use by some Federal agencies (e.g., U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA)) of dosimetry models based upon ICRP recommendations that were either not incorporated in the 1991 rulemaking or were published after that rulemaking.

The SECY-01-0148 paper also discussed options for amending 10 CFR part 20 by adopting the ICRP's recommended occupational dose limits, dosimetric models, and related parameters, and the advantages and disadvantages of the NRC's adoption of the recommendations in ICRP Publication 60 (1991) and the dosimetry models in ICRP Publications 66-69, 71-72, and 74. The paper concluded with an NRC staff recommendation not to amend 10 CFR part 20 at that time, but rather to initiate an effort to study the impacts of adopting the recommended ICRP dosimetry models by through outreach with stakeholders; working with

other Federal agencies through the Interagency Steering Committee on Radiation Standards (ISCORS) to ensure a coherent approach within the United States in radiation protection standards and dosimetric models; developing a technical information basis to provide a better understanding of analytical impacts of possible alternative changes to 10 CFR part 20; and monitoring the work of the ICRP as it develops its revision to implement the ICRP Publication 60 (1991) recommendations.

In the staff requirements memorandum (SRM) to SECY-01-0148, dated April 12, 2002, (ADAMS Accession No. ML021050104), the Commission approved the NRC staff's recommendations to continue to work with and monitor the efforts of other Federal agencies to ensure a coherent approach to U.S. radiation protection standards and dosimetric models and to continue to monitor work of the ICRP. The Commission disapproved the development of a communication plan and a technical information basis. The Commission also directed the NRC staff to continue to consider and grant, as appropriate, licensee requests to use the ICRP Publication 60 (1991) revised internal dosimetry models on a case-by-case basis. As a result, the current NRC regulatory framework is a mixture of radiological standards, concepts and quantities, ranging from the 1959 recommendations in ICRP Publication 1 (1959) to the modeling and numeric values of the 1990 recommendations in ICRP Publication 60 (1991).¹¹

With the issuance of ICRP Publication 103 (2007)¹², the NRC was again presented with the question of whether to update its regulations to reflect the ICRP's recommendations in the area of radiation protection science. This question was addressed in SECY-08-0197, "Options

¹¹ The NRC's current 10 CFR part 20 regulations do not expressly incorporate the recommendations of ICRP Publication 60 (1991) but are based upon the recommendations of ICRP Publications 26 and 30. The NRC's licensees must request use of the ICRP Publication 60 (1991) internal dosimetry models. If approved by the NRC, such a request is treated as an exemption from 10 CFR part 20 regulations. The NRC's authority to grant exemptions is in 10 CFR 20.2301. As a matter of practice, in such exemption approvals, the NRC only authorizes the use of the dosimetric concepts and quantities in the ICRP Publication 60 (1991) recommendations.

¹² The recommended ICRP reference format is "ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4), 2007." The condensed ICRP reference format used throughout this document is: "ICRP Publication 103 (2007)."

to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the ICRP," dated December 18, 2008 (ADAMS Accession No. ML091310193). This paper described and evaluated the ICRP Publication 103 (2007) recommendations along with an NRC staff's recommendation that the Commission approve a closer alignment of the NRC's regulatory framework with the ICRP Publication 103 (2007) recommendations. The NRC staff's recommendation set forth some steps to achieve this alignment, including the development of a technical basis, or the rationale, for a proposed rulemaking to amend the NRC's radiation protection regulations and outreach with stakeholders and interested parties to identify issues, options, and impact information. The NRC staff stated that it would provide the Commission with the results of the stakeholder and interested party interactions, the scope of the proposed rulemaking, including policy and implementation issues, the resources needed for the rulemaking, and the projected rulemaking completion date, which would be dependent on the ICRP's development of essential technical information.

The SECY-08-0197 paper noted that the ICRP Publication 103 (2007) recommendations provided new values for the tissue weighting factors.¹³ The paper also noted that ICRP estimated the following dates and deliverables for updated scientific information and guidance for its new dosimetry system: a. dose conversion factors for calculating occupational exposure from the most commonly used radioisotopes by 2011, b. dose conversion factors for calculating dose limits for members of the public by 2012, and c. dose conversion factors for calculating exposure for all radionuclides by 2014. At present, this information is still being developed. The ICRP's development of biokinetic and dosimetric models and dose coefficients for both worker and public exposure to radionuclides based on the ICRP recommendations was projected for completion by 2014. It is anticipated that this information will not be available until after 2015.

¹³ *Weighting factor* W_T , for an organ or tissue (T) is the proportion of the risk of stochastic effects (i.e., health effects that occur randomly) resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly (10 CFR 20.1003, definition of "Weighting factor W_T ").

As pointed out in SECY-08-0197, the revised dose conversion factors are crucial to any amendment of the NRC's radiation protection framework. These factors could provide the basis for revising the numeric values of weighting factors, ALIs, and DACs contained in the following 10 CFR part 20 requirements: 10 CFR part 20, appendix B, Table 1, "Occupational Values;" 10 CFR part 20, appendix B, Table 2, "Effluent Concentrations;" and 10 CFR part 20, appendix B, Table 3, "Releases to Sewers."

In the SRM to SECY-08-0197, "Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection," dated April 2, 2009 (ADAMS Accession No. ML090920103), the Commission approved the NRC staff's recommended option to begin engagement with stakeholders and interested parties to initiate development of the technical basis for possible revision of the NRC's radiation protection regulations, as appropriate and where scientifically justified, to achieve greater alignment with the ICRP Publication 103 (2007) recommendations. The Commission also directed the NRC staff to continue to participate in national and international forums on radiation protection and to keep them informed of the results of these outreach activities. Notably, the Commission agreed with both the NRC staff and the NRC's 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."¹⁴ In this regard, the Commission stated that from "a safety regulation perspective, ICRP Publication 103 (2007) proposes measures that go beyond what is needed to provide for adequate protection."¹⁵ During the outreach activities associated with the potential alignment with the ICRP Publication 103 (2007) recommendations, the Commission

¹⁴ 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," dated April 2, 2009 (ADAMS Accession No. ML090920103), at 1.

¹⁵ *Id.*

directed the NRC staff to “focus the discussion on discerning the benefits and burdens associated with revising the radiation protection regulatory framework.”¹⁶

The Commission also directed the NRC staff to examine how a lower occupational dose limit of 20 mSv (2 rem) per year has affected the medical and industrial sectors in countries that have implemented the ICRP recommendation when developing the technical basis for the rulemaking. Finally, based on the extent and complexity of the stakeholder comments received, the Commission directed the NRC staff to either (1) provide the Commission with a proposed rule once the technical basis has been developed, or (2) provide a paper to the Commission outlining any substantive policy issues and options for their resolution prior to developing a proposed rule.

In response to the Commission’s direction in SRM-SECY-08-0197, NRC staff conducted stakeholder outreach activities on issues about potential changes to the NRC’s radiation protection regulations. Three *Federal Register* notices were issued requesting public 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 were made at a variety of professional societies, licensee organizations, public interest groups, and State organizations (e.g., Conference of Radiation Control Program Directors and the Organization of Agreement States).

In the fall of 2010, the NRC staff conducted a series of facilitated round table workshops in Washington, DC, Los Angeles, CA, and Houston, TX. Each workshop included representatives from a broad range of users of radioactive material; this process provided an opportunity for various groups of stakeholders to have a focused discussion of the technical issues associated with potential changes to the NRC’s radiation protection standards. The October 2010 workshop in Washington, DC focused on the nuclear power and fuel cycle industries and the radiation protection programs of other Federal agencies (e.g., EPA, DOE,

¹⁶ *Id.*

U.S. Navy, Armed Forces Radiobiology Research Institute, and National Institutes of Health). The November 2010 Los Angeles workshop focused on medical uses of radiation, and the November 2010 Houston, TX workshop focused on industrial radiography. These workshops provided stakeholders the opportunity to discuss the various technical issues with each other and with NRC staff. Transcripts of each workshop and written comments received in response to the *Federal Register* notices are publicly available through the NRC's public Web site on the page entitled, "Options to Revise Radiation Protection Regulations and Guidance," <http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html>.

In addition, the NRC staff's outreach activities included participation in the revision of the International Basic Safety Standards by the International Atomic Energy Agency (IAEA) from 2009 through its completion in the second quarter of 2013, and observation of the revision of the Euratom Basic Safety Standards Directive in the European Union. Both the IAEA's and Euratom's revisions focused on aligning their requirements with the ICRP Publication 103 (2007) recommendations.

After extensive stakeholder engagement, the NRC staff determined that an additional paper to the Commission outlining substantive policy issues was needed. This additional policy paper was provided as SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance," dated April 25, 2012 (ADAMS Accession No. ML121020108). The SECY-12-0064 paper summarized the NRC staff's interactions with stakeholders as directed by SRM-SECY-08-0197, and provided policy and technical guidance on potential revisions to the NRC's radiation protection regulations.

In SECY-12-0064, the NRC staff recommended that the NRC's regulatory framework be amended to reflect the new terminology and dose calculation methodologies to align with national and international scientific approaches for estimating radiation exposure and risk contained in ICRP Publication 103 (2007). The NRC staff, however, recommended that the

NRC not initiate a rulemaking to reflect these changes until the ICRP published its updated dose coefficients and other supporting information, so that a single comprehensive change could be made to the relevant provisions and appendices of 10 CFR part 20. The NRC staff also recommended that the following be explored in greater detail: a reduction in the occupational dose limit to 20 mSv (2 rem) per year, including the mechanisms that would be available to provide some flexibility for licensees to request a higher limit under specified conditions; the impacts of a reduction in the dose limit for the lens of the eye to either 50 mSv (5 rem) or 20 mSv (2 rem), including how the prevention of cataracts should be viewed in comparison with the potential formation of cancer or other adverse impacts; and the impacts of a change in the dose limit for the embryo/fetus to 1 mSv (100 mrem).

Finally, in SECY-12-0064, the NRC staff recommended that: no additional ALARA (as low as is reasonably achievable) planning requirements should be made, however applicable regulatory guidance should be updated to provide additional examples of mechanisms acceptable in the development and implementation of radiation protection programs; the NRC staff should continue to monitor and interact with various international organizations in developing tools and methodologies for assessment of doses in the environment; the NRC staff should explore the implications, benefits, and costs of aligning NRC regulations in 10 CFR part 20 to the NRC metrication policy; and the NRC staff should explore a more detailed examination of the implications, benefits, and costs of requiring additional NRC license categories and Agreement State¹⁷ licensees to report occupational exposures to the NRC's Radiation Exposure Information and Reporting System (REIRS) database.

¹⁷Section 274 of the Atomic Energy Act of 1954, as amended (AEA), authorizes the NRC to relinquish specified authority concerning the regulation of certain radioactive materials to a State, which then assumes regulatory authority over those radioactive materials following the signing of a written agreement between the NRC and the State. Becoming an Agreement State is at the discretion of the State; at present 37 states have Agreement State status. Prior to such relinquishment, the NRC must determine whether the proposed State regulatory program is adequate to protect public health and safety and is compatible with NRC's regulations before it can become an Agreement State. Once Agreement State status is established, the NRC will monitor the Agreement State program.

In SRM-SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance," dated December 17, 2012 (ADAMS Accession No. ML12352A133), the Commission approved in part and disapproved in part the NRC staff's recommendations. Specifically, the Commission approved the NRC staff's development of a draft regulatory basis for a revision to 10 CFR part 20 to align with the most recent methodology and terminology for dose assessment in ICRP Publication 103 (2007), including consideration of any conforming changes to all NRC regulations. The Commission directed the NRC staff to develop improvements in the NRC's guidance for those segments of the regulated community that would benefit from more effective implementation of the ALARA strategies and programs to comply with regulatory requirements. The Commission also directed the NRC staff to continue discussions with stakeholders regarding dose limits for the lens of the eye and the embryo/fetus. In addition, the Commission directed the NRC staff to continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current dose limit. Finally, the Commission directed the NRC staff to improve reporting of occupational exposure by the NRC and Agreement State licensees to the NRC's REIRS database.

In SRM-SECY-12-0064, the Commission disapproved the NRC staff's recommendations to develop a draft regulatory basis to reduce the occupational total effective dose equivalent to 20 mSv (2 rem) per year. The Commission also disapproved the elimination of traditional or "English" dose units to measure radiation exposure from the NRC's regulations. Rather, the Commission directed the continuation of the use of both traditional and International System (SI)¹⁸ units in the NRC's regulations.

Amendments to NRC regulations may require corresponding changes to the regulations of the various Agreement States. The NRC's Agreement State regulations are in 10 CFR part 150. The definitions section of 10 CFR part 150, 10 CFR 150.3, defines the term "Agreement State" as "any State with which the [NRC] or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the [AEA]."

¹⁸ "SI" is the French acronym for "*Le Système international d'unités*" the modern form of the metric system.

In a separate and related activity, the NRC staff will be preparing an ANPR for 10 CFR part 50, appendix I (RIN 3150-AJ38; NRC-2014-0044), which concerns the NRC's design objectives governing dose assessments for radioactive effluents from light-water-cooled nuclear power reactors. The preparation of the 10 CFR part 50, appendix I, ANPR is also in response to the Commission's direction in SRM-SECY-12-0064, which stated that the NRC staff shall, along with the development of the draft regulatory basis for the 10 CFR part 20 regulations, engage in a parallel effort to develop a draft regulatory basis for aligning the 10 CFR part 50, appendix I, design objectives with the most recent methodology and terminology for dose assessment.¹⁹

III. Regulatory Objectives.

In accordance with the Commission's direction provided in SRM-SECY-12-0064, the NRC staff is preparing a draft regulatory basis to support a possible amendment to 10 CFR part 20, and with conforming changes to other NRC regulations to align more closely with the ICRP Publication 103 (2007) dose assessment methodology and terminology. The NRC staff is continuing to hold discussions with stakeholders regarding alternative approaches to ensure individual protection at or near the current dose limit are examined, including considerations of whether revised or additional regulatory requirements and guidance may be appropriate to ensure that cumulative occupational exposures²⁰ are minimized, and whether progressive restrictions should be taken as cumulative exposures increase; whether the dose limits for the lens of the eye should be reduced; whether the dose limits to the embryo/fetus of a declared

¹⁹ The NRC staff has not yet determined whether it will prepare one draft regulatory basis, covering both potential revisions to the 10 CFR part 20 regulations and the 10 CFR part 50, appendix I, design objectives, or two separate bases.

²⁰ The total dose that an occupationally exposed worker receives as a result of repeated exposures to ionizing radiation to the same portion of the body, or to the whole body, over time (<http://www.nrc.gov/reading-rm/basic-ref/glossary/cumulative-dose.html>).

pregnant occupational worker should be reduced; and whether any undue hardships arise as a result of applying the NRC's metrication policy to any amendment of the 10 CFR part 20 regulations. The results of these discussions with stakeholders will be reflected in the draft regulatory basis. Finally, the 10 CFR part 20 draft regulatory basis will consider improvements in the reporting of occupational exposure by the NRC and Agreement State licensees, including those licensees who currently do not currently submit reports to the NRC's REIRS database.

IV. Specific Considerations.

The NRC staff has identified policy and technical issues to guide the development of a draft regulatory basis for the potential revisions to the NRC's radiation protection regulations and guidance as described in Section III of this ANPR. Sections A through F that follow provide a summary of these policy and technical issues. A more detailed discussion of each issue is contained in a series of six issue papers prepared by NRC staff and identified in Section VIII of this ANPR.

A. Update 10 CFR part 20 to align with ICRP Publication 103 methodology and terminology.

Several revisions are under consideration to more closely align the existing NRC regulations in 10 CFR part 20 with the ICRP Publication 103 (2007) methodology and terminology for dose assessment. During the 30-year period of 1977 to 2007, the ICRP published three key radiological protection recommendations, ICRP Publication 26 (1977), ICRP Publication 60 (1991), and ICRP Publication 103 (2007). The current NRC regulatory framework is a mixture of radiological standards, concepts and quantities ranging from the recommendations in ICRP Publication 1 (1959) to the modeling and numeric values of the recommendations in ICRP Publication 60 (1991).

The current 10 CFR part 20 regulations are based primarily upon the recommendations of ICRP Publication 26 (1977); however, there is one difference in terminology worth noting. The ICRP recommendations used the phrases “the sum of the dose-equivalent from external exposure” and “the committed effective dose equivalent from the intake of radionuclides.” The NRC’s regulations use the term “total effective dose equivalent” (TEDE) to represent the summation of dose received from sources external to the body and dose received from the intake of radioactive materials.

In 1991, the ICRP revised its recommendations for dose calculation. The ICRP Publication 60 (1991) recommendations provided changes in the way tissue and radiation weighting factors were defined and used (moving from quality factors to radiation weighting factors). A corresponding change in terminology was also made. For example, ICRP Publication 60 (1991) introduced the term “effective dose,” which was defined as the sum of the weighted equivalent doses in all the tissues and organs of the body.

Additionally, the ICRP Publication 103 (2007) recommendations made revisions to the calculation of dose, including (1) modification of the modeling used for calculation of radiation exposures, (2) changes in values of tissue weighting factors and radiation weighting factors, and (3) substantial modifications of the metabolic models used to represent the movement of radioactive material through the human body. The human body can now be modeled as a more complex set of mathematical and “voxel”²¹ phantoms as a result of advances in medical imaging technology since the last substantial amendment of the 10 CFR part 20 regulations in 1991. These technological advances have resulted in the development of reference computational phantoms that are specific models for adult males and females, 15-year-old males and females,

²¹ Voxel is the shortened term for *volume pixel*, the smallest distinguishable box-shaped part of a three-dimensional image. Voxel images are primarily used in the field of medicine and are developed from x-rays, CAT (Computed Axial Tomography) scans, and MRIs (Magnetic Resonance Imaging) allowing medical professionals to obtain accurate 3D models of the human body. (Reference: Webopedia (www.webopedia.com)).

and for various other age groups, including infants, 1-year-old, 5-year-old, and 10-year-old children. The reference phantoms for the human body are described in general terms in ICRP Publication 103 (2007) and in ICRP Publication 110 (2009).²²

The availability of models for different age groups provides the opportunity to calculate the numeric values for public exposure to effluents in a more comprehensive manner as compared to the previous calculation methodology of basing assessments primarily on an adult member of the public. A general population includes individuals of both genders and various age groups that range from newborns to senior citizens. Over time, an individual matures from infancy to adulthood, which includes various stages of development. Therefore, the scientific community is evaluating the appropriate approach for a member of the public that would account for the period of time spent at different ages so that the long-term risk of exposure to radiological effluents over a number of years can be properly represented. In particular, the ICRP is considering the use of an age and gender weighted dose coefficient for developing a set of values for environmental intake of radionuclides. Similarly, the NRC is also considering revising the definition of the reference person²³ for its use in environmental dose calculations. The NRC is considering the use of the age and gender averaged approach to provide a more realistic representation of a member of the public that explicitly considers the presence of infants and children within the population.

The concept of a reference person may be like the approach documented in the DOE Technical Standard, DOE-STD-1196-2011, "Derived Concentration Technical Standard," dated April 2011 (ADAMS Accession No. ML13323B598). The DOE-STD-1196-2011 calculates derived concentration standards using age-specific effective dose coefficients for reference

²² The ICRP recommended format is: ICRP, 2009. Adult Reference Computational Phantoms. ICRP Publication 110. Ann. ICRP 39 (2), and the condensed format used in this document is: ICRP Publication 110 (2009).

²³ The NRC's regulations use the term "reference man," which means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base (10 CFR 20.1003, definition of "reference man").

members of the public, along with age and gender dependent intake rates for ingestion of water and inhalation of air. The members of the public are represented by six age subgroups (newborns,²⁴ 1-year-old, 5-year-old, 10-year-old, and 15-year-old children and adults). The analysis weights the effective dose coefficients for each subgroup by their fractional representation in the U.S. population and by their intake of the radionuclide through inhalation, ingestion, or air submersion over their lifetimes. The DOE standard is based on the weighting factors and dose coefficients in ICRP Publication 60 (1991).

As part of its development of the draft regulatory basis, the NRC staff will consider revising the regulations in 10 CFR part 20, as well as making conforming changes to other NRC regulations, to incorporate the ICRP term, “effective dose.” The NRC staff recognizes the preference, from a regulatory stability standpoint, for retaining the term “total effective dose equivalent,” but will analyze, in the draft regulatory basis, the advantages and disadvantages of replacing “total effective dose equivalent” with “effective dose” or “total effective dose” in its regulations.

The same terminology as it is used elsewhere in the world may present qualitative benefits of consistency and ease in communication. With regard to the ICRP’s dose assessment methodology recommendations, the NRC staff will consider, in the draft regulatory basis, replacing the definition of “weighting factor” (W_T) in 10 CFR 20.1003 with the tissue weighting factors in Table 3, ICRP Publication 103 (2007), and replacing the quality factors in 10 CFR 20.1004, Tables (B).1 and (B).2, “Units of Radiation Dose,” with the radiation weighting factors in Table 2, ICRP Publication 103 (2007), along with other associated changes (e.g., replacing “dose equivalent” with the term “equivalent dose,” and replacing “effective dose equivalent” with the term “effective dose,” and revising the definition of the term “quality factor”). If approved by the Commission, an update of 10 CFR part 20 to reflect the tissue weighting

²⁴ The DOE standard uses the term “newborn,” while ICRP Publication 103 (2007) uses the term “infant.”

factors and radiation weighting factors from ICRP Publication 103 (2007) would amend these sections.

In addition, as a part of the development of the draft regulatory basis, NRC staff will consider revising the values in appendix B to 10 CFR part 20, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;” Table 1, “Occupational Values;” Table 2, “Effluent Concentrations;” and Table 3, “Releases to Sewers,” with new values for ALIs, DACs, effluent concentrations, and sewer concentrations. The current values in appendix B are based on a public dose limit of 0.5 mSv (50 mrem).

The various types of NRC licenses pose different challenges for the use of methodology and terminology for dose assessment. In some instances, exposures to occupational workers and members of the public at a licensed facility are only from sources external to the body. Conversely, other types of licensed facilities have the potential for significant exposures to occupational workers and members of the public due to intake of radionuclides. These types of licenses would be more directly impacted by the revision of the W_T , ALI, and DAC values. Therefore, the NRC staff is seeking to understand how various proposals for addressing this issue would affect licensee activities. Likewise, the NRC staff wishes to understand the possible impacts of the proposals, and more specifically, the reasons why certain proposals may be difficult to achieve or may undermine radiation protection. Therefore, the NRC staff is seeking to understand the impacts of adopting the ICRP Publication 103 (2007) methodology and terminology into its regulatory program.

The Issue Paper 1, “Update 10 CFR Part 20 to Align with International Commission on Radiological Protection Publication 103 Methodology and Terminology,” ICRP Publication 103, provides a more detailed discussion and is available in ADAMS under Accession No.

ML14084A342. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders.

Questions:

Q1-1: What are the implications of changing the NRC's regulations to specify "total effective dose" in place of the current term "total effective dose equivalent?" To the extent possible, please provide specific implementation and operational cost information on the impacts of this change relative to licensee procedures, training, recordkeeping, and reporting. This information is necessary for the NRC to determine whether the imposition of such requirements on NRC licensees is justified.

Q1-2: If the NRC adopts the dose assessment terminology and methodology of ICRP Publication 103 (2007) in a future rulemaking, what time period should the NRC consider providing for implementation of the ICRP Publication 103 (2007) methodology and terminology?

Q1-3: How should the calculations of effluent concentration, currently in the 10 CFR part 20 radiation protection regulations, be modified to reflect advances in modeling that are now available? In particular, the NRC is interested in preliminary views on the age and gender averaged approach.

Q1-4: Should the public dose limit of 0.5 mSv (50 mrem) continue to be the basis for the effluent concentration limits for the radionuclides in 10 CFR part 20, appendix B, Table 2, Columns 1 and 2? Should it be reduced or otherwise modified?

B. Occupational Dose Limit for the Lens of the Eye.

The ICRP Publication 26 (1977) provided an occupational dose limit of 300 mSv (30 rem) per year for the lens of the eye. During the 1980's, it became clear from epidemiological studies that the risks from radiation exposure were higher than those anticipated when the ICRP Publication 26 (1977) recommendations were published. As a result, in ICRP Publication 60 (1991), the ICRP recommended reducing the occupational dose limit for the lens of the eye to 150 mSv (15 rem) per year, which is 50 percent of the previously recommended limit of 300 mSv (30 rem) per year in ICRP Publication 26 (1977). In its 1991 rulemaking for 10 CFR part 20, the NRC adopted the ICRP Publication 60 (1991) recommendation in 10 CFR 20.1201(a)(2)(i). In addition, the 1991 amendments added a definition of "lens dose equivalent" (LDE), which is the external exposure of the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm²).²⁵

As the ICRP continued to re-examine its radiation protection principles, it noted that the eye is one of the most sensitive organs of the body, that the protection of the eye against the effects of ionizing radiation is designed primarily to prevent the formation of cataracts, and that the most sensitive part of the eye for cataract formation is the lens. Cataract formation falls under the class of radiation effects referred to as deterministic (or tissue reactions as used in ICRP Publication 103 (2007)). At doses above a certain threshold, the severity of cataract formation increases with dose, but the radiation-induced incidence of cataract formation below the threshold dose is believed to be essentially zero.

On April 21, 2011, the ICRP issued a statement on tissue reactions indicating that a review of recent epidemiological evidence suggests that there are some tissue reaction effects, particularly those with very late manifestation, where threshold doses are, or might be, lower than previously considered. For the lens of the eye, the threshold absorbed dose is now

²⁵ 10 CFR 20.1003, definition of "Lens dose equivalent (LDE)."

considered to be 0.50 Gy (50 rad). The ICRP's statement was based on draft report, "Early and Late Effects of Radiation in Normal Tissues and Organs: Threshold Doses for Tissue Reactions and Other Non-Cancer Effects of Radiation in a Radiation Protection Context," which was published on January 20, 2011, by ICRP. The draft report contained information reviewing the early and late effects of radiation in 36 normal tissues and organs with respect to radiation protection. It also provided new estimates of threshold doses for tissue injury in all organ systems, and for morbidity and mortality, following acute, fractionated, or chronic exposure.

On, August 30, 2011, the NRC solicited public comments on the proposed new ICRP recommendations with the publication, "New International Commission on Radiological Protection Recommendations on the Annual Dose Limit to the Lens of the Eye," in the *Federal Register* (76 FR 53847). A summary of stakeholder views on this issue is provided in SECY-12-0064, Enclosure 3, "Assessment of Technical Issues and Feedback," pages 13 through 17 (ADAMS Accession No. ML121020108).

The ICRP revised the January 2011 draft report based on the comments received during the comment period. Its findings were included in ICRP Publication 118 (2012), "ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context," published on August 28, 2012. The ICRP Publication 118 (2012) formalized the new ICRP recommendations for the lens of the eye that are based on the prevention of radiogenic cataracts. For planned occupational exposure situations, the ICRP recommended reducing the limit on equivalent dose for the lens of the eye to 20 mSv (2 rem) per year, averaged over 5 consecutive years (i.e., 100 mSv (10 rem) in 5 years), with no single year exceeding 50 mSv (5 rem), which is significantly lower than ICRP's previous recommendation of 150 mSv (15 rem) per year in ICRP Publication 60 (1991).

The NRC believes that it is appropriate, and scientifically justified, to explore in greater detail the impact of a reduction in the dose limit for the lens of the eye to 50 mSv (5 rem). The NRC also believes that further discussion is warranted on how the prevention of cataracts (which can be corrected by a well-established surgical procedure) compares to efforts to reduce the probability of cancer, a disease posing a far greater health risk. The approaches to be considered include adopting the recommendations in ICRP Publication 118 (2012), moving towards closer alignment with the ICRP recommendations, or retaining the current dose limit. Any new requirements will have implications for measuring occupational exposures and the need to better estimate the dose to the lens of the eye.

The Issue Paper 2, "Occupational Dose Limit for the Lens of the Eye," provides a more detailed discussion and is available in ADAMS under Accession No. ML14084A341. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders to obtain this information.

Questions:

Q2-1: Is closer alignment with or adoption of the ICRP Publication 118 (2012) recommendations regarding the dose limits to the lens of the eye appropriate given the scientific information now available?

Q2-2: How should the impact of a radiation-induced cataract be viewed in comparison with other potential radiation effects?

Q2-3: What mechanisms could be applied to keep the cumulative exposure to the lens of the eye below the threshold of 0.50 Gy (50 rad)?

Q2-4: What methods should be allowed for measurement or assessment of the dose to the lens of the eye?

Q2-5: What methods should be allowed for recording dose to the lens of the eye when the eyes are protected?

Q2-6: What are the potential operational impacts of lowering the annual occupational dose to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)? Would a reduction in the occupational dose limit for the lens of the eye require changes in programs, procedures, practices (e.g., increased use of protective eyewear), or in-room shielding? If so, please describe these changes, including any potential implementation and operational costs.

Q2-7: What are the potential impacts on State regulatory programs of a reduction in the occupational dose limit to the lens of the eye from the current NRC regulatory standard of 150 mSv (15 rem) to 50 mSv (5 rem)?

C. Dose Limit for Embryo/Fetus of a Declared Pregnant Occupational Worker.

Currently, the NRC's regulations in 10 CFR 20.1208(a) set the dose limit for the embryo/fetus of a declared pregnant worker at 5 mSv (500 mrem) for the entire pregnancy. Section 20.1208(d) provides allowances for delays in the declaration of pregnancy by workers. If the dose equivalent to the embryo/fetus has exceeded 5 mSv (500 mrem), or is within 0.5 mSv (50 mrem) of this dose, at the time the worker declares the pregnancy to the licensee, then the dose to the embryo/fetus cannot exceed 0.5 mSv (50 mrem) for the remainder of the pregnancy (10 CFR 20.1208(d)). In addition, licensees are to make efforts to avoid substantial

variation above a uniform monthly exposure rate to satisfy the dose limit (10 CFR 20.1208(b)). These requirements are based on the ICRP Publication 26 (1977) recommendations. However, ICRP Publication 103 (2007) recommends that the dose limit for the embryo/fetus of a declared pregnant worker be the same as that for a member of the public, which is 1 mSv (100 mrem).

Prior to the 1991 amendments to 10 CFR part 20, the NRC's regulations did not contain a specific dose limit for the embryo/fetus of a declared pregnant occupational worker. Instead, as a matter of policy, the NRC used a single annual limit for both genders and relied on information in Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," which was first issued in March 1975 (ADAMS under Accession No. ML13350A220) to maintain exposures to the embryo/fetus ALARA.

In developing Regulatory Guide 8.13, the Commission considered the recommendations in NCRP Report No. 39 (1971), "Radiation Protection Criteria." The NCRP recommended that during the entire gestation period, the maximum permissible dose equivalent to the embryo/fetus from occupational exposure of the worker should not exceed 5 mSv (500 mrem). The ICRP Publication 26 (1977) recommended limiting the working conditions of the declared pregnant worker in such a manner that it is unlikely that the embryo/fetus would receive a dose greater than 5 mSv (500 mrem) for the entire gestation period (51 FR 1092; January 9, 1986).

Thousands of pregnant women are occupationally exposed to ionizing radiation each year. There are radiation-related risks throughout pregnancy that are related to the stage of pregnancy and absorbed dose. Exposure of the embryo/fetus to ionizing radiation could cause adverse health effects, such as cancer and developmental abnormalities. The susceptibility of the embryo/fetus to damage by radiation is well established and data suggests that the period from 10 weeks to 17 weeks in the development of a fetus may be especially critical. Because of this susceptibility, limiting the dose to the embryo/fetus to 5 mSv (500 mrem) or less during the entire pregnancy is generally considered desirable (51 FR 1092; January 9, 1986). Accordingly,

the NCRP Report 54 (1977), "Medical Radiation Exposure of Pregnant and Potentially Pregnant Women," recommended that the total dose equivalent to the embryo/fetus from occupational exposure of the expectant mother not exceed 5 mSv (500 mrem), and that once the pregnancy is known, exposure of the embryo/fetus not exceed 0.5 mSv (50 mrem) in any month.

The ICRP Publication 60 (1991) made clear that the embryo/fetus should be regarded as a member of the public when considering the protection of female workers who are or may be pregnant. In ICRP Publications 60 (1991) and 103 (2007), the ICRP concluded that there is no reason to distinguish between the genders for the purposes of controlling occupational exposures. However, under the ICRP recommendations, if a female worker declares her pregnancy, then additional controls must be considered to protect the embryo/fetus. The ICRP also stated that the methods of radiation protection for occupational workers, who are or may be pregnant, should provide a level of protection for the embryo/fetus equivalent to that provided for a member of the public. The ICRP Publication 103 (2007) recommended approach is that the working conditions of a pregnant worker, after declaration of pregnancy, should be such that it is unlikely that the additional dose to the fetus would exceed about 1 mSv (100 mrem) during the remainder of pregnancy.

On May 24, 2013, NCRP Report No. 174, "Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance," was released. It updated and expanded upon the information in NCRP Report No. 54. The report noted that scientific knowledge has increased and public concerns have changed in the past 36 years since NCRP Report No. 54 was published. Like the findings of ICRP Publication 103 (2007), the report recommended a dose limit of 1 mSv (100 mrem), including dose from the intake of radionuclides, to the embryo/fetus of a declared pregnant worker and recommended applying the concept of ALARA to these exposures.

Although the assessment of doses to the embryo/fetus from exposures to external radiation can be related directly to exposures of the pregnant worker, assessment of doses from intakes of radionuclides is not straightforward. Doses to the embryo/fetus may result from the inhalation or ingestion of radionuclides by the mother during or before pregnancy, and additional doses to the newborn child may result from the transfer of radionuclides in breast milk. The ICRP publications provide dose coefficients for the offspring (embryo/fetus and newborn child) following radionuclide intake by the mother before or during pregnancy and during breast feeding. In many important cases of potential radionuclide intake, doses to the offspring may exceed doses to the mother; such cases should be taken into account in the development of radiation protection programs.²⁶

To provide adequate radiation protection for the embryo/fetus, and to minimize the restriction on employment, the NRC recognized the importance of female workers voluntarily informing their employers of their pregnancy and the estimated date of conception, so that arrangements can be made to restrict potential exposures. The pregnant worker has the fundamental responsibility for deciding when or whether she will formally declare her condition to her employer. This position is derived from court rulings concerning a woman's rights regarding pregnancy. Having a formal declaration of pregnancy derives from legal, not health protection, considerations (56 FR 23373; May 21, 1991). If an occupational worker chooses not to declare her pregnancy, then the licensee will not be required under the Commission's regulations to limit her dose to the 5 mSv (500 mrem).

The undeclared pregnant occupational women are protected under the NRC's regulations for all workers. The normal occupational dose limits would still be in effect and would have to be complied with, and the dose would also have to be kept "as low as is

²⁶ See ICRP Publication 60 (1991); ICRP Publication 75 (1997), "General Principles for the Radiation Protection of Workers;" and ICRP Publication 96 (2005), "Protecting People against Radiation Exposure in the Event of a Radiological Attack."

reasonably achievable.” In addition, as part of her initial employment, the woman, like all occupational workers, should receive instructions in radiation protection (10 CFR 19.12), and a copy of the current version of Regulatory Guide 8.13 (56 FR 23373; May 21, 1991).

The ICRP Publication 103 (2007) recommends that the dose to the embryo/fetus of a declared pregnant worker provide the same general level of protection as that offered for a member of the public, which is 1 mSv (100 mrem). The ICRP recommends applying the 1 mSv (100 mrem) criterion after the declaration of pregnancy by the occupational worker.

The NRC has determined that it is appropriate and scientifically justified to explore whether to change the dose limit for the embryo/fetus to 1 mSv (100 mrem). In its 1991 final rule that amended 10 CFR part 20, the NRC changed the dose limit for a member of the public from 5 mSv (500 mrem) to 1 mSv (100 mrem); however, it did not make the corresponding change to the dose limit for the embryo/fetus. Lowering the dose limit for the embryo/fetus of a declared pregnant occupational worker would align the NRC’s regulatory requirements with current scientific data. The data indicate that the embryo/fetus is more sensitive to radiation than initially surmised. This approach would also align the NRC’s regulations with the ICRP Publication 103 (2007) 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 Issue Paper 3, “Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker,” provides a more detailed discussion and is available in ADAMS under Accession No. ML14084A339. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders to obtain this information.

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? What are the potential implementation and operational costs?

Q3-2: Are there any benefits or impacts associated with applying the reduced dose limit over the entire gestation period, or only to the period after declaration?

Q3-3: Are there any anticipated implementation impacts on recordkeeping if the dose limit to the embryo/fetus is lowered to 1 mSv (100 mrem)? What are the potential implementation and operational costs?

Q3-4: Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP Publication 103 (2007) recommendation difficult in certain circumstances?

Q3-5: Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data?

D. Individual Protection - ALARA Planning.

Each NRC licensee is required to develop, document, and implement a radiation protection program commensurate with the scope and extent of its licensed activities.²⁷ In addition to meeting expressed dose limits, the NRC requires its licensees to apply the ALARA

²⁷ 10 CFR 20.1101(a).

principle to their licensed operations. Section 20.1003 defines the term ALARA as “making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part [10 CFR part 20] as is practical consistent with the purpose for which the licensed activity is undertaken...”²⁸ The NRC’s current ALARA requirements are provided in subpart B of 10 CFR part 20, “Radiation Protection Programs,” and are contained in 10 CFR 20.1101(b) and (d). The current occupational dose limits are provided in subpart C of 10 CFR part 20, “Occupational Dose Limits,” and 10 CFR 20.1201 provides the occupational dose limits for adults.

In the United States, the majority of occupationally exposed individuals receive less than 20 mSv (2 rem) per year as reported to the NRC.²⁹ However, a small percentage of individuals receive larger exposures up to, and occasionally above, the NRC’s current annual occupational limit of 50 mSv (5 rem). While nuclear power reactor operators have been successful in reducing individual exposures, such that only a very limited number of individuals exceed 20 mSv (2 rem) in a year,³⁰ this is not the case in other segments of the regulated community. For example, industrial radiographers have a somewhat greater percentage of individuals above the average annual dose level of 20 mSv (2 rem) recommended in ICRP Publication 103 (2007). Stakeholder interactions have led the NRC staff to conclude that some of these individuals may be receiving doses close to the 50 mSv (5 rem) limit over multiple years. As described in Section IV.E. of this ANPR and Issue Paper 6, “Reporting of Occupational Exposure” (ADAMS Accession No. ML14084A344), detailed information on these cumulative exposures is difficult to ascertain because some segments of the regulated community are not required to report occupational exposure, therefore making it difficult “to assure that lifetime

²⁸ 10 CFR 20.1003 (definition of “ALARA (acronym for ‘as low as is reasonably achievable’”).

²⁹ NUREG-0713, “Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2011” (ADAMS Accession No. ML13095A191).

³⁰ NCRP Report No. 160, “Ionizing Radiation Exposure of the Population of the United States,” 2009.

exposure of workers repeatedly exposed near the limits is minimized” (52 FR 2822; January 27, 1987).

The NRC’s regulation in 10 CFR 20.1101(b) provides that each 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).” The NRC’s current regulations in 10 CFR part 20 do not include an explicit requirement to plan activities to optimize radiation protection (ALARA planning) or to establish ALARA planning values as part of the licensee’s radiation protection program. With respect to nuclear power reactors, the NRC staff has issued Regulatory Guide 8.8, Revision 3, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable” (ADAMS Accession No. ML003739549), which describes methods to implement the existing ALARA requirements, including detailed ALARA planning for use in the operations of commercial power reactors. However, this level of ALARA planning is not as common in the programs of other types of NRC licensees.

The NRC notes that its implementation and enforcement of its ALARA principles are generally made through specific license conditions instead of through more detailed regulations. Therefore, the NRC staff questions whether additional regulatory requirements are appropriate to foster a clear and consistent approach for all types of licensees versus relying upon license conditions.

In SRM-SECY-12-0064, dated December 17, 2012 (ADAMS Accession No. ML12352A133), the Commission directed the NRC staff to continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current dose limit. The NRC is currently examining possible mechanisms for addressing individual protection at, or near, the current occupational dose limit of 50 mSv (5 rem) per year. One

potential mechanism for achieving this goal is to revise 10 CFR 20.1101, "Radiation Protection Programs," to include additional requirements for implementing ALARA. Furthermore, reducing exposures through consistent ALARA implementation is a straight forward method for addressing concerns about a worker receiving a cumulative occupational dose, at or near the dose limit, over a number of years.

In addition, the NRC is interested in other proposals for addressing individual protection at or near the current dose limit. During previous public interactions, some stakeholders expressed an interest in strengthening the current ALARA requirements, whereas others expressed opposition to any additional requirements. Some stakeholders who opposed additional ALARA requirements expressed concerns that such additional requirements would become de facto limits and would inhibit the flexibility of licensees to deal with specific operational circumstances.

The NRC staff believes that the objective of any additional regulatory requirements should be to ensure the accurate monitoring of an individual's cumulative occupational dose and to ensure that progressive measures to reduce dose are taken, if necessary, as the cumulative dose increases. If the NRC determines that additional regulatory requirements are necessary to limit the cumulative occupational dose, then this objective could be achieved through either performance-based requirements, such as ALARA, prescriptive requirements, or both. Performance-based requirements express or describe the particular outcomes that must be achieved while leaving some discretion to a licensee on the specific mechanisms used to achieve those outcomes. On the other hand, prescriptive requirements specify a particular methodology or action that is necessary for compliance.

The establishment of ALARA planning values in administrative control levels, relative to the implementation of the ALARA principle, is not a new concept. The "Federal Radiation Protection Guidance for Occupational Exposure" (52 FR 2822, January 27, 1987; ADAMS

Accession No. ML13269A320), provides a set of recommendations that incorporates this concept. The NRC and several other Federal agencies developed these recommendations, which were approved by President Reagan on January 20, 1987. The guidance states, "Federal radiation guidance can address only the broad prerequisites of an effective ALARA program ... authorities may find it useful to establish or encourage the use of ... administrative control levels specifying, for specific categories of workers or work situations, dose levels below the limiting numerical values recommended in this guidance."

The current regulations do not require licensees to have a structured ALARA planning process. Therefore, the NRC is considering the development of a requirement for ALARA radiation protection planning. This additional ALARA planning requirement would provide a basis to ensure that licensees have an ongoing process to review radiation exposures, to consider if changes are warranted and practical to reduce exposures, and to ensure the implementation of appropriate programmatic changes.

In conjunction with developing a requirement for ALARA planning, the NRC is considering developing a mechanism to address additional protection when an individual occupational worker nears his or her annual dose limit, and developing cumulative dose criterion that would control doses that an individual worker may receive over a multiple-year period. In this regard, the NRC would require each licensee, as a part of its radiation protection program, to establish mechanisms to examine cumulative occupational doses, and to implement control measures limiting additional doses if an occupational worker approaches his or her cumulative dose criterion. If the NRC ultimately issues such a requirement, it would develop associated guidance to address the various types of licensed activities.

Specifically, regulatory guidance could describe the types of methodologies that the NRC staff could consider acceptable to meet the regulatory requirement of controlling dose as an individual occupational worker approaches the annual dose limit, or his or her cumulative

dose criterion. The NRC is considering using various methodologies that are based on national and international recommendations. One potential methodology could be for a licensee to use the ICRP Publication 103 (2007) recommendations for an average dose over a 5-year period of 20 mSv (2 rem) as an administrative control level (ACL).³¹ If no individual at the licensed facility exceeded the ACL on an annual basis, then no additional actions would be needed by the licensee other than continued monitoring of exposures. However, if an individual exceeded the ACL in any particular year, the licensee could commit to tracking and limiting the dose of that worker over a 5-year period; the licensee would need to maintain the cumulative occupational dose records during this period.

A second potential methodology for establishing an ACL could be based on the NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," which recommended an age based cumulative dose restriction. The NCRP Report 116 recommended an occupational dose limit of 50 mSv (5 rem) per year and a cumulative occupational dose limit of 10 mSv (1 rem) times the individual's age in years. Therefore, a licensee could establish an ACL at the 10 mSv (1 rem) level, and if this level is exceeded in any one year, the licensee would apply cumulative dose tracking to ensure that the cumulative age based dose limit for the individual is not exceeded.

In a third potential methodology, a licensee could establish an ACL based on lifetime exposures instead of the yearly approach to dose limits as in ICRP or NCRP recommendations. Under this approach, a licensee could commit to tracking the cumulative occupational doses for each worker and to applying specific additional restrictions if the cumulative occupational dose exceeded a set lifetime cumulative ACL value. Example values of cumulative ACL, such as 0.5 Sv (50 rem) or 0.75 Sv (75 rem), over the worker's lifetime could serve as appropriate fractions

³¹ The 1987 "Federal Radiation Protection Guidance for Occupational Exposure" defines an "administrative control level" as a requirement "determined by a competent authority of the management of an institution or facility. They are not primary limits, and may therefore be exceeded, upon approval of competent authority or management, as situations dictate" (52 FR 2833; January 27, 1987).

of the upper (tolerable) cumulative lifetime dose limit found in ICRP and NCRP recommendations. This approach could work in conjunction with regulations for cumulative occupational dose recordkeeping requirements to ensure that licensees took appropriate actions if dose limits are exceeded.

The preceding methodologies are presented as possible approaches for implementing a general performance requirement. Alternatively, the regulation could specifically incorporate one or more of these methodologies as a new prescriptive requirement. The NRC is interested in obtaining stakeholder input on the use of a performance or prescriptive approach, the rationale as to why one approach is preferable over the other, and any other alternatives that the NRC should consider as acceptable.

The NRC is also considering whether an additional requirement is necessary to address the question of concurrent occupational doses of an individual working at multiple licensed facilities. Situations may occur in which workers receive occupational exposures at more than one facility concurrently. One approach could be to expand the scope of 10 CFR 20.2104(a) to cover workers' concurrent employment by two or more licensees during the same period of time (e.g., a weekday shift at one licensee's facility followed by a weekend shift at another licensee's facility). Presently, the regulations require licensees to determine the yearly occupational doses received by its workers. In this regard, 10 CFR 20.2104(c) could be revised to add the phrase "and any concurrent" to statements that now only specify the individual's most recent employer.

As discussed previously, before the 1991 amendments to 10 CFR part 20, the NRC's regulatory framework included the formula $D=5(N-18)$, where " N " is the person's age in years, and where " D " is the lifetime dose limit in rems.³² As part of the implementation of this former

³² The former regulation, 10 CFR 20.101(b)(2), stated "[t]he dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 ($N-18$) rems where ' N ' equals the individual's age in years at his last birthday." The 1991 rulemaking revised and renumbered the NRC's radiation protection regulations in 10 CFR part 20.

regulation, workers were required to provide NRC Form 4, "Cumulative Dose History Report," when reporting to a new facility. However, the 1991 amendments to 10 CFR part 20 removed this requirement and the lifetime dose limit formula. The statement of considerations for the 1986 proposed rule (which led to the 1991 final rule) explains the lifetime dose limit formula was eliminated as a measure to reduce annual and lifetime doses to occupational workers (51 FR 1092, 1121; January 9, 1986). As a result, there is now no requirement in the NRC's regulations for a licensee to receive a cumulative dose history report (NRC Form 4 or equivalent) from a new employee.

The various types of radioactive material licenses pose different challenges to the control of occupational doses (e.g., industrial radiography, nuclear medicine). In some situations, the design and operation associated with the use of radioactive material limits the occupational dose. Conversely, some uses of radioactive materials can result in significant occupational doses that may be near the annual dose limit. Therefore, the spectrum of radioactive material licenses presents a wide range of challenges and opportunities for reducing occupational doses under ALARA provisions, especially when exposures approach the limits. The NRC is seeking to understand how to ensure that a greater focus is placed on keeping occupational doses ALARA, consistent with the wide range of uses of radioactive material that are licensed. The NRC also seeks to understand the potential impacts of the methodologies that were previously discussed, including any potential difficulties associated with implementation if such methodologies were made requirements by rulemaking.

The Issue Paper 4, "Individual Protection - ALARA Planning," provides more detailed information and is available in ADAMS under Accession No. ML14084A340. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders to obtain this information.

Questions:

Q4-1: What are the potential implications of adding specific ALARA planning and implementation requirements to the 10 CFR part 20 regulations? What changes to licensee radiation protection programs could be anticipated? What would be the potential implementation and operational costs?

Q4-2: What regulatory language should be used for an additional ALARA planning requirement and what is the rationale for this language?

Q4-3: How does each of the described methodologies for addressing when an individual occupational worker approaches his or her cumulative dose for the year work for different classes of licensed uses (e.g., a worker at a nuclear reactor power plant versus an industrial radiographer versus medical personnel)? What are the benefits and impacts of the various approaches to ALARA planning on the various types of licenses?

Q4-4: Should licensees be allowed to establish different ACLs for different groups of occupational workers? If so, what should be the basis for the various groupings?

Q4-5: How do the different methodologies previously discussed impact the ability of licensees to best address radiation protection within their programs?

Q4-6: Other than the methodologies discussed in the preceding section, are there other ways to evaluate occupational lifetime cumulative exposures that should be considered?

Q4-7: What are the potential impacts to licensees, contractors, and dosimetry vendors of amending 10 CFR 20.2104 to require a licensee to account for exposure from an occupational worker's concurrent employment with another licensee? Are there any dosimetry vendors that provide concurrent dose records? Should the NRC consider provisions that would require individual occupational workers to provide their occupational dose information in addition to requiring such information from licensees?

Q4-8: Should the Agreement States be allowed to use more restrictive or prescriptive requirements if the NRC decides to use a performance-based approach? What are the benefits and impacts of the various methodologies discussed in the preceding section on Agreement State regulatory programs and Agreement State licensees? If the NRC issues a proposed rule, this information will be important in establishing an appropriate Agreement State compatibility level for any proposed regulatory requirements.

E. Metrication - Units of Radiation Exposure and Dose.

The current 10 CFR part 20 radiation protection regulations were promulgated approximately 1 year before to the publication of the NRC's metrication policy (57 FR 46202; October 7, 1992). The metric system is also known as the International System of Units (SI). Therefore, most NRC dose limits and other units of measurements are listed in the regulations with the traditional or "English" (also known as non-SI) units first followed by the metric units in parentheses. Some NRC regulations list metric units first followed by traditional or "English" units in parentheses. Numerical information in the appendices to 10 CFR part 20 is a mixture of traditional and metric units. For example, the DACs in 10 CFR part 20, appendix B, Table 1, are in units of microcuries per milliliter ($\mu\text{Ci/ml}$); therefore, the activity is in traditional units and the

volume is in metric units. By contrast, appendix C of 10 CFR part 20 only displays numerical information using the traditional units of measurement.

In SRM-SECY-12-0064, the Commission disapproved the elimination of traditional units from the NRC's regulations. The SRM further stated that both the traditional and SI units should be maintained. Pursuant to the NRC's 1992 metrication policy, the NRC supports and encourages the use of the metric system of measurement by the nuclear industry. The 1992 policy directed the NRC staff, beginning in 1993, to publish the following documents in dual units of measurement with the SI units listed first followed by the "English" units in parentheses: 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. In addition, the NRC's policy provided that licensee-specific NRC documents, such as licensee inspection reports and licensee-specific docketed material, use the system of measurements utilized by the licensee. Furthermore, the policy provided that all event reporting and emergency response communications between licensees, the NRC, and State and local authorities will use the traditional units of measurement. In a 1996 review of its 1992 metrication policy, the Commission stated that it does not intend to revisit the 1992 policy unless it is shown to cause an undue burden or hardship (61 FR 31169, 31171; June 19, 1996).

The implementation of the NRC's metrication policy is not consistent with respect to the units of measurement used in recordkeeping and reporting. The NRC's regulations in 10 CFR 20.2101(a), "Records," currently require licensees to use the traditional units. Therefore, licensees cannot use the metric units even if they wanted to do so. Section 20.2101(b) allows licensees to record quantities in SI units in parentheses after the traditional units. Section 20.2101(c) requires information recorded on shipping manifests, (e.g., shipments to low-level waste disposal facilities) as required by 10 CFR 20.2006(b), to be listed in SI units or both SI

and traditional units. In addition, some NRC regulations require licensee reports to present information with the traditional units first followed by the SI units in parentheses.

The requirement to keep all records in traditional units, or in both sets of units, could be seen as inconsistent with a revised regulation in which the dose criteria are expressed first in SI units followed by the traditional units. One alternative could be to amend the regulations to allow a licensee to maintain records in either set of units as long as only one set of units was used throughout a licensee's recordkeeping system. Another alternative could be to allow a licensee to use either set of units in measurements and calculations; however, the licensee would be required to present the final values that support regulatory compliance in one or both sets of units. These various alternatives have different regulatory burdens and implementation issues. The NRC staff is seeking to gain additional information from stakeholders on the implications of the various alternatives, including the option that no change should be made.

As part of its draft regulatory basis development for a possible revision to the 10 CFR part 20 regulations, the NRC staff is examining the implementation of the Commission's metrication policy about how numerical material could be presented in appendix B of 10 CFR part 20. The NRC staff believes that the unique nature of appendix B, with its detailed numeric information for each radionuclide, may pose a situation in which a deviation from the metrication policy may be needed.

Two issues need to be addressed regarding the application of the Commission's metrication policy to appendix B to 10 CFR part 20. The first issue is the selection of the value that the NRC will consider as the regulatory standard. The values in appendix B are currently given in traditional activity units (microcuries (μCi)) with a certainty of one significant digit. One microcurie is equal to 3.7×10^4 becquerels (Bq) in the SI units; therefore, the conversion from microcurie to becquerel is completed by multiplying the activity in microcuries by 3.7×10^4 . The resulting values in SI units (becquerels) could be more or less restrictive than the original

microcurie values depending on the number of significant digits to which the value is rounded. For example, currently appendix B to 10 CFR part 20 provides the oral ingestion *ALI* for *Actinium-224* as $2 \times 10^4 \mu\text{Ci}$. The corresponding value in the SI units before rounding to one significant digit is $7.4 \times 10^7 \text{ Bq}$. If rounded to one significant digit, using the standard rounding conventions, the value in Bq would be smaller than the value in microcurie, and would be more restrictive. Therefore, the NRC staff is exploring the implications of stating the numerical values in appendix B of 10 CFR part 20 like that used in in appendix A to 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials."

In the development of appendix A to 10 CFR part 37, the NRC stated that the SI units provided the regulatory standard and the traditional units were provided for practical use only. Appendix A to 10 CFR part 37 provides in column 1 the name of the radioactive material, column 2 provides the source activity in terabecquerel (TBq), and column 3 provides the source activities in curies. In appendix A to 10 CFR part 37, the NRC also chose to forgo the conventional rounding to the nearest whole number or the rounding to the first significant figure after the decimal point. Rather, appendix A to 10 CFR part 37, column 3 lists curie activity equivalents as three significant figures because many NRC licensees use curies instead of becquerels for source radioactivity. The 10 CFR part 37 -approach of rounding to three significant figures greatly reduces any discrepancies between the two values (the source strength in curies and the source strength in becquerels).

The second issue is the presentation of numerical information in the appendices to 10 CFR part 20. If the NRC staff implements the Commission's metrication policy in appendix B to 10 CFR part 20 (i.e., SI units listed first followed by traditional units in parentheses), the table could become more complicated. At present, appendix B of 10 CFR part 20 consists of three columns providing each radionuclide's name, symbol, and the solubility class, followed by six additional columns providing each radionuclide's ALIs and DACs, concentration limits for

airborne and liquid effluents released to the general environment, and concentration limits for discharges to sanitary sewer systems in microcuries or microcuries per milliliter.

Implementation of the metrication policy would effectively add six additional columns to provide the traditional unit numeric counterpart for each value in parentheses next to the corresponding values in the SI units. An alternative could be to publish the traditional unit values in a separate guidance document for the convenience of users; this alternative would be an exception to the Commission's metrication policy.

The NRC staff is interested in stakeholder views on potential options on the application of the Commission's metrication policy to any potential 10 CFR part 20 revisions. Specifically, the NRC staff is seeking input on: (1) what are some of the potential options; (2) what are the impacts of the option on the format and the usefulness of the NRC's regulations; and (3) what are some of the impacts of the option on licensee operations, especially any benefits, burdens, or undue hardship. Using two units of measurements, traditional and SI units has the potential for causing communication challenges. Therefore, the NRC staff is interested in the implications and impacts of aligning any potential revisions to 10 CFR part 20 with the Commission's existing metrication policy, and with other possible changes that could be considered as aligning to such a change.

The Issue Paper 5 "Metrication - Units of Radiation Exposure and Dose," provides more detailed information and is available in ADAMS under Accession No. ML14084A343. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders.

Questions:

Q5-1: Will promulgation of amendments to the 10 CFR part 20 regulations with dose limits and other measurements shown in dual units, with the SI units shown first, followed by the traditional units in parentheses, cause an undue burden or hardship upon any licensee or class of licensees? If so, please explain and provide examples, including any potential implementation or operational costs.

Q5-2. Should 10 CFR 20.2101(a) be revised to allow licensees the option of providing records in SI units or in traditional units? Should licensees be allowed to provide reports in the units used in licensee records? Should licensees be required to record and report in both sets of units? Please provide reasons why or why not.

Q5-3. Should the NRC amend the appendices for 10 CFR part 20 to show values in SI units only, in traditional units only, or in both sets of units? If both SI and traditional units are provided, which set of units should be considered as the regulatory standard? If only one set of units is specified, what would be the most effective means to provide the other set of units (e.g., in a separate guidance publication)? Please provide reasons why or why not.

F. Reporting of Occupational Exposure.

On December 19, 1968, the AEC published an amendment to 10 CFR part 20 in the *Federal Register* (33 FR 18926) that added new 10 CFR 20.407, "Personnel exposure and monitoring reports."³³ This new section required the reporting of occupational radiation

³³ In a final rule dated September 29, 1978 (43 FR 44827, 44829), the NRC renumbered 10 CFR 20.407 as 10 CFR 20.408. Section 20.408 later became the basis for current 10 CFR part 20 reporting regulation, 10 CFR 20.2206,

exposure information to a central repository at AEC headquarters. The amendment required four categories of licensees to report: (1) commercial nuclear power reactors, (2) industrial radiographers, (3) fuel processors and fabricators, and (4) manufacturers and distributors of byproduct material. The Commission considered these licensees to have the greatest potential for significant occupational doses. The AEC established this reporting requirement to assist in the following actions: (1) identifying those individuals who are monitored by more than one licensee or AEC contractor, (2) analyzing radiation exposure experience and identifying general exposure trends from year to year, (3) analyzing the exposure experience of AEC contractors and the four listed categories of licensees, (4) initiating appropriate remedial action where trends or experience in increased radiation exposures indicate the need for more effective controls, and (5) considering and developing appropriate modifications to radiation protection standards and requirements.

On January 19, 1975, the NRC was formed and on May 30, 1975, the NRC published a proposed rule in the *Federal Register* (40 FR 23478) that would require all NRC-specific licensees to submit personnel monitoring data to the agency. By a letter dated June 2, 1975 (43 FR 44827), a copy of the notice of the proposed rule was mailed to all NRC-specific licensees (e.g., well loggers, medical and academic institutions, industrial radiographers, and portable gauge users). Thirty-six comments were received on the proposed rule. The majority of the comments supported the proposed rule, but offered suggestions for improvement. Medical licensees raised the majority of the opposition to the proposed rule. Their opposition was based on the following issues: (1) additional paperwork would increase the cost of health care; (2) the personnel monitoring data might have theoretical value, but no practical value; (3) the NRC failed to demonstrate a sufficient cost versus benefit ratio for another administrative

which lists seven categories of licensees required to submit an annual report of the results of individual monitoring of occupational exposure.

requirement; (4) occupational exposures (in medical diagnosis and therapy) are already ALARA; (5) the requirements for reporting overexposures are adequate; (6) only licensees with repeated overexposures should be required to submit annual reports; (7) separating exposures received from NRC-licensed material from exposures received from non-NRC-licensed materials is not possible; and (8) personnel monitoring data contain inherent inaccuracies.

In response to these comments, in a letter dated August 25, 1976, the NRC requested that all NRC-specific licensees voluntarily submit personnel monitoring data for calendar year 1975, along with the total cost for preparing the data in man-hours and dollars-cents. The licensees' responses indicated a total man-hours cost median of 2.75 minutes, and \$0.65 per monitored individual to collect the requested information (NUREG-0419, "Occupational Radiation Exposure at NRC-Licensed Facilities 1975, Office of Standards Development, U.S. Nuclear Regulatory Commission").

After a series of amendments in the 1980s, the occupational reporting requirements in 10 CFR part 20 eliminated the provisions for all NRC-specific licensees to submit reports, and expanded the license reporting categories from four to the current seven, which are: (1) commercial nuclear power reactors, (2) industrial radiographers, (3) fuel processors and fabricators, (4) manufacturers and distributors of certain byproduct material, (5) geologic repositories for high-level waste (HLW), (6) independent spent fuel storage installations (ISFSIs) and (7) facilities for the land disposal of low-level waste (LLW) (46 FR 13978, February 25, 1981; 46 FR 58282, December 1, 1981; and 47 FR 57480, December 27, 1982).

The current occupational reporting provisions were moved to 10 CFR 20.2206, "Reports of Individual Reporting," as a part of the 1991 amendments to 10 CFR part 20. Section 20.2206 requires seven categories of licensees to provide an annual report of the monitoring of occupational dose each April 30th (covering the prior calendar year) to the NRC's REIRS database. At present, five categories of NRC licensees report information to the database,

namely: (1) commercial nuclear power reactors; (2) industrial radiographers; (3) fuel processors (including uranium enrichment facilities), fabricators, and reprocessors; (4) ISFSIs; and (5) manufacturers and distributors of certain byproduct material. The NRC's REIRS database does not include occupational information for the two other reporting categories, LLW and HLW facilities, because the NRC has no licensees in those categories. As a result, the database provides a system for maintaining all relevant occupational doses received at nuclear power reactors, fuel processors and fabricators, and ISFSIs in the United States, because all of these facilities are licensed by the NRC regardless of whether they are (even if located in an Agreement State).

Currently, a reporting gap exists because industrial radiographers, and manufacturers and distributors of certain byproduct material, who hold Agreement State licenses, instead of NRC licenses, are not subject to the reporting requirements in 10 CFR 20.2206. As described in the following paragraphs and Section VII.B., Issue Paper 6, "Reporting of Occupational Exposure" (ADAMS Accession No. ML14084A344), Agreement States are not required to adopt the provisions in 10 CFR 20.2206. Consequently, the NRC has experienced significant difficulty in developing reasonable assessments of the overall occupational doses received from industrial radiographers, and manufacturers and distributors of certain byproduct material, since the majority of these licensees are regulated by Agreement States. In addition, as identified in the chart in Section V of Issue Paper 6, several categories of NRC radioactive material licensees are not subject to the 10 CFR 20.2206 reporting requirements. Therefore, the NRC lacks occupational exposure data for several categories of radioactive material licensees.

The NRC's regulations in 10 CFR 20.2206(b) require certain categories of NRC licensees to submit an annual report of the results of the monitoring required by 10 CFR 20.1502 to the NRC's REIRS database. The NRC does not require Agreement States to adopt the 10 CFR 20.2206 provisions. Although an Agreement State can choose not to require their

licensees to submit annual reports of occupational radiation dose information to either itself or the NRC, some Agreement State licensees voluntarily report occupational dose information to the REIRS database.

In addition, to expand the Agreement State occupational radiation dose information contained in the NRC's REIRS database, on August 6, 2010, the NRC sent a letter to Agreement State Radiation Control Programs (ADAMS Accession No. ML102100390). This letter requested Agreement State assistance in obtaining occupational radiation dose information from their licensees in the categories of industrial radiography and nuclear pharmacy for the monitoring period of 2000 through 2009.

During the period of 1997 through 2010, the NRC received occupational dose reports from 312 Agreement State licensees. The 312 licensees represented less than 2 percent of the total number of Agreement State licensees, at that time. The NRC staff review of the reports indicated that the 312 Agreement State licensees monitored exposures of 40,622 occupational workers, and 78 percent (31,704) of these occupational workers received a measurable dose. The complete NRC staff review is available in NUREG-2118, Vol.1, "Occupational Radiation Exposure at Agreement State-Licensed Materials Facilities, 1997-2010" (ADAMS Accession No. ML12220A081).

Increased use of the NRC's REIRS database, could serve as a national occupational exposure database for both the NRC and Agreement States. If properly implemented, the database could correlate the occupational exposure of an individual to the licensed facility where the exposure was received. This information would be especially useful for those workers who work concurrently at more than one licensed facility, especially in the radioactive materials area. All of the nuclear power plant licensees are regulated by the NRC, and are required to report occupational exposures to the NRC's REIRS database. Therefore, it is possible to determine the occupational doses of nuclear workers that are employed at more

than one nuclear facility, including determining whether a person is exceeding the occupational dose limits. However, there is no mechanism for the NRC or an Agreement State to determine whether an individual is exceeding the occupational dose limits as a result of concurrent employment at multiple licensed facilities, especially if the individual works in jurisdictions regulated by both the NRC and one or more Agreement States.

For example, a physician whose medical practice involves the use of radioactive materials could work concurrently in Washington, DC (an NRC jurisdiction), Alexandria, VA (an Agreement State jurisdiction), and Bethesda, MD (a different Agreement State jurisdiction). If Agreement State licensees provided reports to the NRC's REIRS database, then it would be possible to ensure that an individual who is concurrently employed by licensees in multiple jurisdictions does not exceed the occupational dose limits.

Moreover, increased use of the NRC's REIRS database by NRC and Agreement State licensees, could serve a vital function in evaluating the overall effectiveness of the NRC's regulatory programs, and could be used by the NRC and Agreement States in inspection, enforcement, and incident response activities. It could also assist in assessing cumulative occupational doses on a national basis. The NRC staff is considering if new categories of licensees should be required to report to the database and how to effectively integrate any new reporting from NRC and Agreement State licensees into the system. Therefore, the NRC staff is pursuing that a more detailed examination of the implications, benefits, and costs of requiring additional categories of licensees to report exposures to the NRC's REIRS database. The Issue Paper 6, "Reporting of Occupational Exposures," provides a more detailed discussion of the background and proposals on the reporting of occupational doses to the database including a chart in Section V that lists several categories of NRC radioactive material licensees where input is needed from the public. In addition, the following questions are intended to elicit information from the public, the regulated community, and other stakeholders.

Questions:

Q6-1: What criteria should the NRC use to identify additional categories of licensees that should be required to submit annual occupational exposure reports under 10 CFR 20.2206(a)?

Q6-2: What are the benefits of collecting occupational exposure information in one central database to assess the total annual occupational exposure of those individuals who work at more than one licensed facility or contractor facility during the calendar year and receive occupational exposures at these facilities?

Q6-3: Should Agreement States be required to adopt regulations that are compatible with the requirements in 10 CFR 20.2206?

Q6-4: Should the NRC consider a gradual expansion of the 10 CFR 20.2206 licensee reporting categories in a step-wise fashion (e.g., staggered compliance dates for different categories of licensees)? What are the advantages or disadvantages for this option?

Q6-5: What are the potential implementation and operational costs associated with expanding the occupational exposure reporting requirements?

V. Public Meetings.

The NRC plans to hold a series of Category 3 public meetings specific to the six issues identified in this ANPR. The public meetings will be held during the ANPR public comment period. The public meetings will provide forums for the NRC staff to discuss the issues and questions identified in the ANPR with external stakeholders and to receive information to support development of a draft regulatory basis for a potential revision of the radiation protection requirements in 10 CFR part 20. The NRC does not intend to provide detailed responses to comments or other information submitted during the public meetings. Each public meeting will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web site for additional information about the public meetings at <http://www.nrc.gov/public-involve/public-meetings/index.cfm>. The NRC will post the notices for the public meetings and may post additional material related to this action to the Federal rulemaking Web site at www.regulations.gov under Docket ID NRC-2009-0279. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2009-0279); (2) click the "Sign up for E-mail Alerts" link; and (3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

VI. Cumulative Effects of Regulation.

The NRC has implemented a program to address the possible “cumulative effects of regulation” (CER) in the development of regulatory bases for rulemakings. The CER describes the challenges that licensees or other impacted entities (such as Agreement States) may face while implementing new NRC or other agency regulatory requirements. The CER is an organizational effectiveness challenge that results from a licensee or other impacted entity implementing a number of complex positions, programs, or requirements within a prescribed implementation period and with limited available resources, including the ability to access technical expertise to address a specific issue. The NRC is specifically requesting comment on the cumulative effects that may result from a potential amendment to 10 CFR part 20. In developing comments on the possible cumulative effects of any future 10 CFR part 20 rulemaking, please consider the following questions:

(1) In light of any current or projected CER challenges, what could be considered as a reasonable effective date, compliance date, or submittal date(s) from the time any potential final rule is published to the implementation date of any new requirements, including changes to programs, procedures, or facilities?

(2) If there are current or projected CER challenges, what could be done to address them (e.g., if more time is anticipated to implement the potential new requirements, what period of time is estimated to be sufficient, and why would such a proposed time frame be necessary)?

(3) Please identify any current or projected regulatory actions by the NRC or another regulatory agency (such as new or amended regulatory requirements or orders) that could potentially influence the implementation of any potential 10 CFR part 20 rulemaking?

(4) Are there any possible unintended consequences resulting from a potential 10 CFR part 20 rulemaking, such as the possibility that this potential rulemaking could create conditions

that would be contrary to the potential action's purpose and objectives? If so, what are the anticipated consequences and how could they be addressed?

(5) Is there any potential costs and benefits information available at this time on a potential 10 CFR part 20 rulemaking?

VII. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this ANPR to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on this ANPR and the draft regulatory basis issues papers (see Section VIII of this ANPR) with respect to the clarity and effectiveness of the language used.

VIII. Availability of Documents.

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

DOCUMENT	ADAMS Accession No./Web Link
The ICRP Publications referenced in this ANPR are copyright protected. The NRC cannot reproduce or provide copies of these documents. For additional information regarding obtaining copies of ICRP Publications, please see the ICRP Web site.	http://www.icrp.org/publications.asp
The NCRP Publications referenced in this ANPR are copyright protected. The NRC cannot reproduce or provide copies of these documents. For additional information regarding obtaining copies of NCRP Publications, please see the NCRP Web site.	http://www.ncrponline.org/Publications/Publications.html

DOCUMENT	ADAMS Accession No./Web Link
Issue Paper 1: Update 10 CFR Part 20 to Align with International Commission on Radiological Protection Publication 103 Methodology and Terminology.	ML14084A342
Issue Paper 2: Occupational Dose Limit for the Lens of the Eye.	ML14084A341
Issue Paper 3: Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker.	ML14084A339
Issue Paper 4: Individual Protection - ALARA Planning.	ML14084A340
Issue Paper 5: Metrication - Units of Radiation Exposure and Dose.	ML14084A343
Issue Paper 6: Reporting of Occupational Exposure.	ML14084A344
A Review of the History of U.S. Radiation Protection Regulations, Recommendations, and Standards," by C.G. Jones, <i>Health Physics Journal</i> , February 2005, Vol. 88, No. 2, pages 105-126.	ML050400427
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," dated August 2, 2001.	ML011580363
SRM - 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," dated April 12, 2002.	ML021050104
SECY-08-0197, "Options To Revise Radiation Protection Regulations And Guidance With Respect To The 2007 Recommendations of ICRP," dated December 18, 2008.	ML083360555
SRM - SECY-08-0197, "Options To Revise Radiation Protection Regulations And Guidance With Respect To The 2007 Recommendations of ICRP," dated April 2, 2009.	ML090920103
SECY-12-0064, "Recommendations For Policy And Technical Direction To Revise Radiation Protection Regulations And Guidance," dated April 25, 2012.	ML121020108
SRM -SECY-12-0064, "Recommendations For Policy And Technical Direction To Revise Radiation Protection Regulations And Guidance," dated December 17, 2012.	ML12352A133
Regulatory Guide 8.8, Revision 3, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable."	ML003739549

DOCUMENT	ADAMS Accession No./Web Link
DOE Technical Standard, DOE-STD-1196-2011, "Derived Concentration Technical Standard."	ML13323B598
"Federal Radiation Protection Guidance for Occupational Exposure" (52 FR 2822; January 27, 1987).	ML13269A320
Regulatory Guide 8.13 "Instruction Concerning Prenatal Radiation Exposure," March 31, 1975.	ML13350A220
NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2011."	ML13095A191
NUREG-2118, "Occupational Radiation Exposure at Agreement State-Licensed Materials Facilities," 1997-2010.	ML12220A081

X. Rulemaking Process.

The NRC will consider comments received or other information submitted in response to this ANPR in the development of the proposed draft regulatory basis or any other documents developed as a part of any potential 10 CFR part 20 rulemaking. The NRC, however, does not intend to provide detailed responses to comments or other information submitted in response to this ANPR. The information obtained through this ANPR process will be used to develop a draft regulatory basis. The draft regulatory basis will be published for public review and comment. If the NRC develops a regulatory basis sufficient to support a proposed rule, then there will be an opportunity for public comment when the proposed rule is published and the NRC will respond to such comments if and when it publishes a final rule. If the NRC develops draft supporting guidance for a proposed 10 CFR part 20 rulemaking, then the public, the regulated community, and other stakeholders will have an opportunity to provide comment on the draft guidance.

If the NRC decides not to pursue a 10 CFR part 20 rulemaking on this topic, the NRC will publish a document in the *Federal Register* that will generally address public comments and withdraw this ANPR.

Dated at Rockville, Maryland, this 8th day of July, 2014.

For the Nuclear Regulatory Commission.

Mark A. Satorius,
Executive Director for Operations.

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