[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, 34, 35, 40, 50, 53, 61, 71, and 72

[NRC-2025-1140]

RIN 3150-AL47

Reforming and Modernizing the NRC's Radiation Protection Framework

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern its standards for protection against radiation. These proposed revisions would address section 5(b) of Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," and would reflect the NRC's experience and other developments in the field of radiation protection since the NRC's last major revisions to these standards in 1991. In addition, the NRC is issuing for public comment draft implementing guidance.

DATES: Comments must be submitted electronically using https://www.regulations.gov by 11:59 p.m. eastern time on **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by Docket ID NRC-2025-1140, at https://www.regulations.gov. If your material cannot be submitted using

https://www.regulations.gov, call or email the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on https://www.regulations.gov to view public comments.

You can read a plain language description of this proposed rule at https://www.regulations.gov/docket/NRC-2025-1140. 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: Caylee Kenny, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-7150; email: Caylee.Kenny@nrc.gov.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The NRC is proposing revisions to its Standards for Protection Against Radiation to address section 5(b) of Executive Order (E.O.) 14300 and to support national policy objectives stated therein. The revisions to the NRC's Standards for Protection Against

Radiation reflect the agency's reconsideration of its use of the linear no-threshold (LNT) model for assessing health effects from radiation exposure and its application of the "as low as is reasonably achievable" (ALARA) principle that is predicated on LNT. Additionally, the proposed revisions reflect the agency's consideration of shifting to a regulatory framework that uses predominately determinate radiation limits to protect from deterministic and stochastic health effects of radiation exposure. The intent of these revisions is twofold and directed at enabling the safe use of nuclear technology while maintaining reasonable assurance of adequate protection from the health effects of radiation exposure and reflecting on several decades of experience since the last major revisions to the NRC's Standards for Protection Against Radiation. In particular, as further discussed below, the proposed revisions would (1) address unnecessary conservatism and excessive subjectivity in regulatory requirements as they relate to protection from very low doses of radiation, and (2) apply the NRC's considerable regulatory experience to incorporate flexibility and acceptable alternatives in the regulations while maintaining reasonable assurance of adequate protection from the health effects of radiation exposure.

The NRC has determined that certain aspects of its radiation protection standards allow for excessive subjectivity that leads to overly conservative assessments, and thus, are in tension with the NRC's Principles of Good Regulation (see SECY-25-0031, "Mission Statement Implementation Guidance" (ML25106A351)), in particular, the "Efficiency," "Clarity," and "Reliability" principles. Therefore, the NRC is proposing changes to its regulations and guidance to reduce subjectivity and unnecessary burden on applicants and licensees and to increase flexibility associated with the licensing and use of nuclear technology while maintaining reasonable assurance of adequate protection of public health and safety. Specifically, the NRC has determined that the LNT model may lead to conservative implementation of radiation protection measures at low

doses. Consequently, the NRC proposes to remove references to the ALARA principle, which rests on the LNT model's assessment of risks from very low doses of radiation, from its regulations; instead, the NRC would apply a less-subjective, graded approach to managing doses below regulatory limits.

Since the proposed changes would predominantly affect regulations in title 10 of the *Code of Federal Regulations* (10 CFR) part 20, "Standards for Protection Against Radiation," they would impact all categories of NRC licensees, and, to the extent that the affected regulations are required for an adequate and compatible Agreement State program, these proposed changes would impact Agreement States. In addition, the proposed changes would support the safe use and deployment of nuclear technologies while continuing to maintain reasonable assurance of adequate protection of individuals and are founded on a holistic consideration of the NRC's regulatory experience and the current state of science using a weight of scientific evidence decision-making approach, as described in E.O. 14303, "Restoring Gold Standard Science."

B. Major Provisions

Major provisions of the proposed rule are the following:

1. Remove ALARA requirements from the regulations in 10 CFR Chapter I*,* and apply a graded approach to dose management framework that involves determinate thresholds for radiation protection, methods for dose management, and acceptable dosimetry methods.
2. Establish a process, called the planned occupational dose limit extension, whereby individuals can exceed certain annual occupational dose limits as long as certain actions are taken and the resultant doses are maintained below multiyear limitations.

3. Introduce a reporting threshold for required monitoring results related to occupational dose limits.
4. Replace unplanned overexposure reporting criteria for public and occupational effective dose limits with a 5-year dose assessment.
5. Allow for variances in public dose limits and/or accessible dose rates on a case-by-case basis, with the implementation of adequate controls.
6. Enable the optional use of modern dose modeling/calculation methods.
7. Apply a 10-rem design-basis accident acceptance criterion to consequence analyses in Regulatory Guide (RG) 1.183 and retire the use of the “well-within” and “small fraction of” standards.
8. Allow licensees to use NRC-approved devices for respiratory protection and certain deviations for these devices without separate licensing actions.
9. Introduce revised threshold/constraint for control of radiological effluents to ensure ample margin with the public dose limit and support of environmental policy objectives, while providing a burden reduction and flexibilities for licensees.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule, as well as qualitative factors to be considered in the NRC’s rulemaking decision. The draft analysis concluded that the proposed rule would result in net cost savings to the industry, Agreement State regulators and the NRC. The key findings of the analysis related to the proposed changes are as follows:

- Cost savings to the industry of approximately $9.53 million/year at a 7 percent discount rate
- Cost savings to the Agreement State regulators of approximately

$244,000/year at a 7 percent discount rate

- Cost savings to the NRC of approximately $704,000/year at a 7 percent discount rate

- The draft regulatory analysis also includes a qualitative discussion of factors that were not quantifiable, including precise cost savings and benefits, if the NRC adopts the rule.

The draft regulatory analysis finds that this proposed rule provides cost savings while maintaining exposure to ionizing radiation within safe limits.

For more information, please refer to the draft regulatory analysis cited in the Availability of Documents section.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-1140 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 website:** Go to https://www.regulations.gov and search for Docket ID NRC-2025-1140.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. 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:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.
- **Public Meeting:** The NRC will conduct a public meeting to describe the proposed amendments and answer questions from the public on this proposed rule. NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website within 10 calendar days of the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: https://www.nrc.gov/public-involve/public-meetings/index.cfm.

B. Submitting Comments

Comments must be submitted using https://www.regulations.gov by 11:59 p.m. eastern time on **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Please include Docket ID NRC-2025-1140 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov as well as enter the comment submissions into ADAMS. 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. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” which requires the NRC to take a number of actions to help provide the American people with safe, abundant nuclear energy. Section 2, “Policy,” of E.O. 14300 sets forth the policy of the United States to (a) reestablish the United States as the global leader in nuclear energy; (b) facilitate increased deployment of new nuclear reactor technologies; (c) facilitate the expansion of American nuclear energy capacity from approximately 100 gigawatts (GW)

in 2024 to 400 GW by 2050; (d) employ emerging technologies to safely accelerate the modeling, simulation, testing, and approval of new reactor designs; (e) support the continued operation of, and facilitate appropriate operational extensions for, the current nuclear fleet, as well as the reactivation of prematurely shuttered or partially completed nuclear facilities; and (f) maintain the United States' leading reputation for nuclear safety. Section 5, "Reforming and Modernizing the NRC's Regulations," of E.O. 14300 requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(b) of E.O. 14300, which requires the NRC to "reconsider reliance on the linear no-threshold (LNT) model for radiation exposure and the 'as low as reasonably achievable' standard, which is predicated on LNT," and states, "[i]n reconsidering those limits, the NRC shall specifically consider adopting determinate radiation limits." A fulsome explanation of how this rulemaking addresses section 5(b) of E.O. 14300 is provided next.

III. Background

Introduction

The NRC is proposing revisions to its standards for protection against radiation to address section 5(b) of Executive Order (E.O.) 14300, "Ordering the Reform of the Nuclear Regulatory Commission," to support the national policy objectives stated in that E.O. and to improve the regulation of the civilian nuclear energy industry, consistent with the aims of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act). All NRC licensees are subject to the NRC's radiation protection requirements set forth in title 10 of the *Code of Federal Regulations* (10 CFR) part 20, "Standards for Protection Against Radiation." These requirements are designed to protect both members of the public and occupational workers from harm that

could be caused by exposure to radiation resulting from a licensee's use of radioactive materials. The proposed revisions to the NRC's standards for protection against radiation reflect the agency's reconsideration, based on current scientific knowledge and regulatory experience, of its use of the linear no-threshold (LNT) model for assessing health effects from radiation exposure and its use of the "as low as is reasonably achievable" (ALARA) principle that is predicated on the LNT model. Additionally, the proposed revisions reflect the agency's consideration of shifting to a regulatory framework that uses predominately determinate radiation limits to protect from deterministic and stochastic health effects of radiation exposure. These proposed revisions are twofold and reflect the NRC's several decades of experience since the last major revisions to 10 CFR part 20 and would enable the safe use of nuclear technology while maintaining reasonable assurance of adequate protection from the health effects of radiation exposure. Specifically, the proposed revisions would (1) address unnecessary conservatism and excessive subjectivity associated with regulatory requirements as they relate to protection from very low doses of radiation, and (2) incorporate flexibility and acceptable alternatives in the regulations.

At present, there are several factors, such as global competition in the development of advanced, energy-intensive technologies like artificial intelligence, that—combined with a national emergency in energy production as described in E.O. 14156, "Declaring a National Energy Emergency"—demand urgent action by the NRC to ensure that the NRC continues to enable the safe use of nuclear technology while maintaining reasonable assurance of adequate protection of the public health and safety. Historically, when establishing or revising its standards for protection against radiation, the NRC, as well as its predecessor, the Atomic Energy Commission (AEC), has stated that the standards are subject to change, considering factors such as the development of new scientific knowledge or further regulatory experience (see 22 FR 549, Jan 29,

1957 and 56 FR 23360, May 21, 1991).

As a result of its consideration of current scientific knowledge and regulatory experience, the NRC has determined that certain aspects of its standards for protection against radiation allow for excessive subjectivity that leads to overly cautious assessments regarding radiological risk and methods to mitigate that risk, and that some aspects of the standards are susceptible to selective or inconsistent enforcement. Such an outcome is inconsistent with the NRC's Principles of Good Regulation, in particular, the "Efficiency," "Clarity," and "Reliability" principles. Specifically, correcting over-conservatisms in the NRC's regulatory framework would help ensure that the NRC's regulatory activities are consistent with the degree of risk reduction achieved, and increasing objectivity would help ensure that regulated entities and the public are more readily able to understand NRC requirements and plan activities accordingly. Moreover, a more objective regulatory framework would contribute to increasing accountability for the NRC in fairly administering its radiation protection standards and lend stability to nuclear regulation. Therefore, the NRC is proposing changes to its regulations and guidance that reduce subjectivity in the implementation and enforcement of the NRC's regulations, reduce unnecessary burden on licensees, and increase flexibility associated with the licensing and use of nuclear technology, all while maintaining reasonable assurance of adequate protection of the public health and safety.

Since the proposed changes would predominantly affect regulations in 10 CFR part 20, they would apply to all categories of NRC licensees. To the extent that the affected regulations must be adopted for an Agreement State to maintain an adequate and compatible Agreement State program, these proposed changes would impact Agreement States. The proposed changes would support the safe use and deployment of nuclear technologies while continuing to maintain reasonable assurance of adequate protection of individuals. The proposed changes are based on a comprehensive

evaluation of the NRC's regulatory experience and the current state of scientific knowledge using a weight of scientific evidence decision-making approach, as described in E.O. 14303, "Restoring Gold Standard Science."

Radiation Protection Standards

Current Standards for Protection Against Radiation

The NRC's standards for protection against radiation in 10 CFR part 20 were last significantly revised in 1991 (56 FR 23360, May 21, 1991), with minor revisions being implemented since that time. For example, the NRC introduced changes in areas such as license termination criteria and respiratory protection in 1997 (62 FR 39058, July 21, 1997) and 1999 (64 FR 54543, October 7, 1999), respectively. In short, the 1991 revisions culminated with the Commission adopting, with some exceptions, the 1977 recommendations from International Commission on Radiation Protection (ICRP) Publication 26. These revisions marked a significant departure from the approach to radiation protection that the NRC and its predecessor, the AEC, had followed since the 1950s. The most significant technical change was the adoption of the concept of "effective" dose, a concept that uses a series of correction factors to translate the risk associated with any type of radiation exposure to a dose as if it were given to the entire body. Effective dose is particularly important for predicting and limiting the stochastic effects of radiation exposure (i.e., health effects, such as cancer, whose occurrence is random in nature). As described in the proposed rule for the 1991 revisions of 10 CFR part 20 (51 FR 1092, May 21, 1991), prior to those revisions, regulatory limits were derived from implicit judgements on health effects associated with the use of licensed materials; but in the 1991 revisions, these limits were derived from an increased understanding of the risk of health effects from radiation exposure. For example, the 1991 revisions set the occupational limit for stochastic effects such that the risk of a

worker dying from cancer that resulted from occupational exposure to radiation was roughly equivalent to the mortality risk experienced by workers in industries not involving radiation exposures.

As described in the NRC's 1991 final rule, the radiation protection standards were revised based on the following key assumptions: (1) within the range of exposure conditions usually encountered in radiation work, there is a linear relationship, without threshold, between dose and the probability of stochastic health effects (such as latent cancer and genetic effects) occurring; (2) the severity of each type of stochastic health effect is independent of dose; and (3) nonstochastic radiation-induced health effects (i.e., health effects whose occurrence is not random in nature, but rather is based on exceeding an empirically determined threshold dose) can be prevented by limiting exposures so that doses are below the thresholds for their induction. The first and second assumptions imply that the potential health risk associated with radiation exposure is proportional to the dose received and that there is an incremental health risk associated with even small doses. Additionally, the second assumption implies that the severity of a stochastic health effect is not related to the radiation dose received by an individual. Finally, the third assumption implies that there are some health effects for which there is a threshold, meaning that the health effect does not occur if the dose to an individual remains below that threshold value. For such nonstochastic effects (now known as tissue effects), determinate limits are appropriate because the threshold for the effects can be reliably established through observation or experimentation, and thus, a limit can be established below which the effect would not occur.

As it relates to stochastic effects, when the NRC issued its 1991 revisions, the Commission observed, based on studies available at the time, that "there is an increased incidence of certain cancers associated with radiation exposure at high doses and high dose rates. However, whether these effects occur at very low doses and, if they

occur, whether their occurrence is linearly proportional to dose are not firmly established." Therefore, the NRC determined that as a policy matter, in the absence of convincing evidence that there is a dose threshold or that the health effects of low levels of radiation are fully understood, the LNT model for cancers and genetic effects was appropriate for formulating radiation protection standards and planning radiation protection programs.

Developments in Radiation Protection Relevant to the NRC's Radiation Protection Regulatory Framework

ICRP Publication 26

The ICRP is an independent organization of members in all fields of radiation protection. It publishes recommendations and guidance regarding radiation protection.

In ICRP Publication 26, the ICRP provided its 1977 recommendations. This was a watershed event in the field of radiation protection. Prior to these recommendations, much of radiation protection was based on limiting the external exposure to individuals and limiting the amount of intake of radioactive materials to radionuclide-specific maximum concentration levels. With the 1977 recommendations, the ICRP introduced the distinction between stochastic health effects and nonstochastic health effects, and it also introduced several new quantities for measuring radiation dose (i.e., equivalent dose and effective dose). Thereafter, the primary focus of radiation protection became protection from those effects that show a threshold and thus whose occurrences are not random in nature (i.e., nonstochastic, or tissue, effects) and protection from those effects that do not show a threshold and whose occurrence is random in nature (i.e., stochastic effects), as opposed to the older approach that essentially focused on protection from internal and external exposures. In ICRP Publication 26, to assess the level of risk, the health effects of internal and external exposures were combined into the concept of effective doses, a quantity that is weighted for types of radiation and organs irradiated,

as applicable. This system was largely adopted by the NRC in its 1991 revisions to 10 CFR part 20 and has served as the basis for the NRC's radiation protection regulatory framework ever since.

ICRP Publication 60

At the time that the NRC was developing its 1991 revisions to 10 CFR part 20, the ICRP was in the process of revising its 1977 recommendations. This culminated with the issuance of ICRP Publication 60 in which the ICRP introduced several refinements to the 1977 methods for calculating doses and recommended revised limits for members of the public and occupationally exposed individuals. As it pertains to the recommended public dose limits, the ICRP initially published its new recommendations in 1985. During the development of its 1991 revisions to 10 CFR part 20, which occurred throughout the 1980s, the NRC integrated the new ICRP recommendations for exposure of members of the public into the 1991 rule.

With regard to the occupational dose limit for stochastic effects, the ICRP reduced its recommended limit from 5 rem/year (50 mSv/year) to 2 rem/year (20 mSv/year) averaged over 5 years, not to exceed 5 rem (50 mSv) in any single year. The NRC decided not to follow this recommendation in the 1991 rule for exposure of workers, based on the NRC's regulatory experience. With ICRP Publication 60, the ICRP also introduced changes to several quantities that are significant to dosimetry calculations. For example, the radiation weighting factor was introduced to replace the quality factor in the conversion of absorbed dose to equivalent dose (called dose equivalent in ICRP Publication 26). This change improved the accuracy of calculations because, rather than calculating the biological effects at a given point in an organ as was done with the quality factor, the radiation weighting factor provides values that are averaged over an entire organ. Additionally, several subsequent supporting publications for ICRP Publication 60 (e.g., ICRP Publication 67) sought to improve the biokinetic

models used to calculate doses and to provide updated derived limits, like annual limits on intake and radionuclide-specific dose conversion factors.

ICRP Publication 103

The most recent updates to the ICRP's comprehensive recommendations for a system of radiological protection, as of 2026, are contained in ICRP Publication 103, published in 2007. In ICRP Publication 103, the ICRP maintained its recommended dose limits and maintained justification, limitation, and optimization as the fundamental principles of radiation protection. Additionally, the ICRP updated its recommended tissue weighting factors and its recommended methodology for accounting for detrimental impacts on overall health, and it provided a framework for demonstrating radiological protection of the environment. The NRC has not incorporated the recommendations in ICRP Publication 103 as requirements into its regulations; however, as explained in the sections describing the proposed regulations at § 20.1010 and at Appendix H to 10 CFR part 20, the NRC proposes in this rulemaking to allow applicants and licensees to use dosimetry modeling approaches that differ from those underlying the current 10 CFR part 20, including those that result from ICRP Publication 103.

NCRP 180 and Commentaries 26 and 27

The National Council on Radiation Protection and Measurements (NCRP) is a technical organization dedicated to the development of recommendations that pertain to public policy involving radiation protection. The NCRP holds a Congressional Charter under Public Law 88-376 to support radiation protection by providing independent analysis, information, and recommendations.

The NCRP's latest major set of recommendations for managing exposure to ionizing radiation is provided in NCRP 180, published in 2018. NCRP 180 is largely consistent with the recommendations in ICRP Publication 103 and reflects advances in the understanding of the biological effects of ionizing radiation that have accrued since

the NCRP published its last major set of recommendations in 1993. In NCRP 180, the NCRP concluded that the consensus understanding of radiation effects has not changed in a way that significantly impacts recommended numeric protection criteria from the 1990s—which are consistent with the NRC's current regulations—except potentially in the case of dose to the lens of the eye. Specifically, the NCRP recognized that there is a growing body of evidence that health effects to the lens of the eye may occur at lower dose levels than previously estimated, potentially impacting currently accepted threshold values. Additionally, the NCRP observed that some research indicates that vision-impairing cataracts might be better characterized as a stochastic health effect rather than a tissue effect (i.e., a nonstochastic effect that is subject to a threshold). On this topic, NCRP Commentary 26 (2016) recognizes that available data does not yet support a quantitative estimate of a new threshold value.

Separately, the current observations from the ICRP, in ICRP Publication 118, concluded that a nominal threshold of 50 rad (0.5 Gy) for the lens of the eye is appropriate. NCRP Commentary 26 provides updated guidance on radiation dose limits for the lens of the eye, reflecting new scientific evidence on cataract formation at lower doses. The commentary recommends reducing the occupational dose limit for the lens of the eye from 15 rem/year (150 mSv/year) to 5 rem/year (50 mSv/year). This recommendation aligns with international recommendations, including those from the ICRP. However, at the time of this rulemaking, these findings are preliminary and the recommendations are conservative in nature, especially when considering that the current annual limit on dose to the lens of the eye is already less than half of the new nominal threshold observed by the ICRP. Further research in this area may merit reconsideration of the current occupational dose limit for the lens of the eye in the future.

Recent Rulemaking Activity Pertaining to 10 CFR Part 20

In April 2002, the NRC staff commenced an effort to update 10 CFR part 20 to

align with what would become the ICRP Publication 103 recommendations. With 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” (ML011580363), the staff presented the Commission with options and recommendations for agency action in response to radiation protection-related information that had been developed since the last major revisions to 10 part 20 in 1991. In response, the Commission directed the staff to coordinate with other federal agencies to ensure that a coherent approach would be applied to the use of updated radiation protection-related information and to monitor the work of the ICRP as it develops what would become ICRP Publication 103.

In December 2008, after the release of ICRP Publication 103, the NRC staff, in SECY-08-0197, “Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the International Commission on Radiological Protection” (ML091310193), recommended that the NRC’s radiation protection framework be amended to align with ICRP Publication 103. As part of that recommendation, the staff observed that rulemaking would not begin immediately because information required for developing the technical basis for the rulemaking and the regulatory analysis was not available at the time. In response, the Commission directed the staff to “immediately 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 2007 recommendations of the [ICRP] contained in ICRP Publication 103.”

In April 2012, after much stakeholder engagement regarding potential changes to the NRC’s radiation protection regulatory framework, the NRC staff, in SECY-12-0064, “Recommendations for Policy and Technical Direction to Revise Radiation Protection

Regulations and Guidance" (ML121020108), communicated to the Commission policy recommendations and the technical basis for revisions to that framework. In response, the Commission approved the development of a regulatory basis for the revision of 10 CFR part 20 and 10 CFR part 50, Appendix I to align those regulations with the most recent methodology and terminology for dose assessment. However, the Commission disapproved the staff recommendations to develop a basis for reducing the limit on occupational total effective dose equivalent and to eliminate the use of traditional units in favor of International System of Units (SI) for radiological measurement. The Commission also directed the staff to continue discussions with stakeholders regarding dose limits for the lens of the eye and for the embryo/fetus. Finally, the Commission directed the staff to continue discussions with stakeholders on alternative approaches regarding radiological protection for individuals at or near the dose limit.

Subsequently, in July 2014, the NRC staff published an advance notice of proposed rulemaking (ANPR) (79 FR 43284, July 25, 2014) to obtain input on its proposed approach to the rulemaking. In response to the ANPR, the NRC received 90 individual comments and about 3,000 form letters. The staff assessed that most of the comments were not supportive of the revision to 10 CFR part 20 in large part because of doubts regarding the safety benefits of the proposed changes when weighed against the costs of implementing the proposed changes.

Finally, in December 2016, as described in SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities" (ML16028A189), and its accompanying Federal Register notice (81 FR 95410), as part of an agencywide reprioritization initiative, the NRC discontinued this rulemaking activity—having concluded that, "the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment."

Petition for Rulemaking Regarding the Linear No-Threshold Model and Standards for Protection Against Radiation

In February 2015, the NRC received three petitions for rulemaking (PRMs) requesting that the NRC amend 10 CFR part 20 to discontinue the use of the LNT model as the primary scientific basis for the NRC's radiation protection standards. The NRC published a Federal Register notice docketing the PRMs (80 FR 35870, June 23, 2015) and requested public comments. The PRMs sought several specific changes to the regulations, such as the increase of the occupational dose limit from 5 rem to 10 rem; the removal of the concept of ALARA based on the assertion that radiation exposure is beneficial at low doses; the increase of the public dose limit so that it would match the proposed occupational dose limit; and the ending of the use of lower dose limits for pregnant women, an embryo/fetus, and children under 18 years of age.

Upon consideration of the PRMs and associated comments from the public and other governmental agencies and the relevant positions of authoritative scientific bodies, the NRC denied the PRMs. In its denial (86 FR 45923, August 17, 2021), the NRC reviewed the scientific basis for its current regulatory framework and the relevant recent research in the area. A key basis asserted by the PRMs was the concept of hormesis (i.e., that low doses of radiation are beneficial to humans), and that, because of this, the NRC's regulatory framework should be revised to reflect the beneficial nature of low dose exposures for workers and members of the public.

The NRC ultimately denied the PRMs, noting, "There is scientific uncertainty and no compelling evidence as to whether the hormesis concept is valid for application to radiation protection requirements. None of the national and international authoritative scientific advisory bodies … support the hormesis concept as a regulatory model for radiation protection" (86 FR 45923). With respect to the argument in the PRMs that the concept of ALARA should be removed from the NRC's regulations, the NRC described

the intended implementation of ALARA as involving the concept of reasonableness (i.e., "making 'every reasonable effort' to implement ALARA … to the 'extent practical'"). Notwithstanding public comments regarding the PRMs, which argued that the NRC's implementation of ALARA has led to excessive costs to licensees and has inhibited the growth and innovation of the nuclear sector, the denial explained that compliance with the ALARA requirement is based on whether the licensee has incorporated reasonable measures to track and, if necessary, to reduce exposures—not whether exposures and doses represent an absolute minimum or whether the licensee has used all possible methods to reduce exposures.

While this description of the ALARA requirement remains true today, the NRC recognizes that there have been challenges in the implementation of the ALARA requirement, namely a lack of clarity of when dose reduction is deemed sufficient, excessive subjectivity, and susceptibility for selective or inconsistent enforcement. For example, there is wide variance within the U.S. nuclear industry in how much a given licensee is willing to spend to reduce radiation exposure and regulatory experience indicates that, in general, these industry-determined benchmarks significantly exceed the value promulgated by the NRC in NUREG-1530. Accordingly, the direction in section 5(b) of E.O. 14300 provides an opportunity for the Commission to correct the implementation issues associated with ALARA, consistent with the "Efficiency," "Clarity," and "Reliability" principles of the NRC's Principles of Good Regulation.

NRC Response to E.O. 14300 Section 5(b)

The NRC considers its current standards for protection against radiation to be science-based to the extent that adequate methods and analyses have been applied in the works that have been referenced in the development of the NRC's regulations and guidance. However, as has been known for many decades, the uncertainty associated with dosimetric models and methods increases significantly in the low dose range. This

is largely because these models and methods rely in part on extrapolations from high-dose and high-dose-rate data as the primary basis for estimation of radiation-related risk at low doses. Such extrapolations of epidemiological data do not fully account for what is known to be a complex, and likely adaptive, cellular response to doses in the low dose range—which includes levels common to NRC-licensed activities—thus, a degree of scientific judgement is used to account for these effects.

Difficulties with using epidemiological data to estimate radiation-related risk at low doses can be attributed to multiple factors. For example, there is difficulty in conducting epidemiological studies with sufficient statistical power to control for confounding factors such as lifestyle choices (e.g., smoking and diet) and population health in order to distinguish between cancers caused by very low level radiation and the large baseline cancer rate to which humans are subjected. For example, Table 12-4 of the BEIR VII Phase 2 report shows that 20 percent of the U.S. population is expected to die from solid cancers (i.e., excluding blood cancers like leukemia). This large baseline cancer rate essentially introduces a signal-to-noise problem with the “signal,” or the fatal cancers from very low doses of radiation, are masked by the large “noise,” from the baseline fatal cancer rate. From a radiobiological perspective, there are unknowns involving cellular defense mechanisms and how these mechanisms modify the long-term health effects of radiation exposure. The scientific community has sought to address these uncertainties in part by adjusting the slope of the linear approximation of the dose-response relationship through the use of a dose and dose rate effectiveness factor (DDREF). However, the appropriate value of the DDREF is itself subject to uncertainty and is the result of scientific judgement. More importantly, the implementation of the DDREF has not had a practical impact on recommended radiation limits or upon curtailing practices that seek to reduce radiation risk by minimizing exposures even to very low doses.

Thus, while the methods used to establish the basis for the NRC's radiation protection standards are sound, and while these standards are protective of the public health and safety, there are uncertainties associated with the methods and resulting recommendations within consensus-based standards, including their exact degree of conservatism. Regulatory experience, though, has demonstrated that the primary issue is not the standards themselves, but their implementation. For example, those standards that go beyond what is necessary for reasonable assurance of adequate protection and that can be interpreted as requiring continuous dose reductions even to very low doses of radiation have often been applied without a reasonable stopping point. In these instances, the radiation protection standards have led to outcomes that are overly conservative. As a practical matter, such over conservatism can significantly undervalue the benefits of activities when compared to their risks, sometimes at great economic costs or stifling of innovation.

Reconsideration of LNT and ALARA

The LNT model of radiation protection has led to confusion regarding the risks associated with low doses of radiation exposure and to unintended consequences as it relates to the costs associated with radiation protection at levels common to NRC-licensed activities. This model is used to account for the stochastic nature of some radiogenic health effects. It combines knowledge from epidemiological data from atomic bomb survivors and other cohorts and radiobiological research results to establish a relationship between the amount of radiation dose that a human receives and the health outcome, in particular cancer. The ICRP describes how epidemiological data from high doses are used to predict risk at very low doses:

> The LNT model receives considerable, although not decisive, support from epidemiological studies of radiation-related cancer risk, in the same sense that the risk of mortality and morbidity from all solid cancers combined in the LSS [Life Span Study] is proportional to radiation dose down to about 100 mGy [10,000 mrad], below which statistical variation in baseline risk, as well as small

> and uncontrollable biases, increasingly tend to obscure evidence concerning any radiation-related risk. This uncertainty is the main reason why it is generally impossible to determine, on epidemiological grounds alone, that there is, or is not, an increased risk of cancer associated with radiation exposures of the order of a few tens of mSv [1 mSv = 100 mrem] and below. Risk estimates for such exposures are obtained through the use of mathematical models that assume a simple relationship, e.g., linear, linear-quadratic, or linear with a dose and dose rate effectiveness factor (DDREF) between risk at higher doses, where epidemiological data tend to be informative, and at doses so low that direct epidemiological observation is uninformative (ICRP Publication 103, paragraph A179).

The radiation dose response relationship is commonly accepted to be linear with changes in slope at lower doses, represented by the DDREF, indicating less health impact per unit dose at lower doses. To date, no threshold has been established in this model, meaning that as the dose decreases to zero, the corresponding risk follows proportionally to zero. However, this lack of a threshold and the proportional relationship between dose and health response are commonly distilled to mean that even the lowest dose will increase the risk of cancer. While this conclusion is technically consistent with the LNT model, it is overly simplistic and leads to confusion because it discounts the effect of known biological responses to cellular upsets and the margins of error associated with slope factors and cancer coefficients that, at low levels of dose, include zero health effects as a possibility.

The NRC recognizes that the quantitative estimation of health risk at very low doses presents longstanding scientific challenges. The NRC acknowledges that advances in radiobiology have identified mechanisms such as DNA damage response and repair, dose-rate effects, and adaptive cellular responses that complicate simple linear extrapolation. However, the NRC finds that no consensus-supported, regulation-ready alternative model to the LNT model exists at this time. In the absence of such a suitable replacement, the NRC has taken this opportunity to address the LNT model's inherent limitations by carefully examining its unintended impact on ALARA practices.

Because of the LNT model's limitations in the very low dose region of the model

(sometimes referred to as linear to zero), the radiation protection community has taken a layered precautionary approach, traditionally seeking to minimize radiation exposure in order to minimize the risk of stochastic health effects. Initially, the intent of this practice was to reduce dose “as low as practicable,” as described in ICRP Publication 1, the 1959 “Recommendations of the International Commission on Radiological Protection.” Subsequently, it was recast to emphasize reasonable approaches to dose reduction, first as “as low as is reasonably achievable” and then as the present-day practice of “optimization.” However, regulatory experience corroborates the observations in E.O. 14300 regarding the negative consequences of relying on subjective interpretations of reasonableness as it relates to risks from and protective measures for very low doses of radiation. The root of the matter is that there is a difference between eliminating all risks and recognizing when a risk exists but is extremely small, or even within the margin of error that includes zero risk, and that further risk reduction is not reasonable.

The ALARA principle is an outgrowth of applying the LNT model. That is, because the LNT model does not recognize a threshold below which stochastic health effects do not occur, there is an implication that dose should be minimized to also minimize the risk of health effects. However, properly understood, the ALARA principle recognizes that, unless all dose is eliminated, some risk may remain but that the level of that risk should be balanced by the reasonableness of further dose reduction measures. In contrast, over-conservatism in the application of the LNT model at very low doses combined with the potential for enforcement action for noncompliance renders implementation of the model susceptible to rote attempts at dose reduction rather than an approach tempered by a measured consideration of the reasonableness of those reductions. In essence, the reasonableness test that is supposed to be inherent to ALARA-related decision-making has gradually become an expectation that if a means of dose reduction is available, regardless of its reasonableness in relation to the total dose

and the amount of reduction, it should be applied without further consideration. In practice, this has at times resulted in significant economic costs and operational and licensing inefficiencies without commensurate public health and safety gains.

This seemingly singular focus on minimizing the risk associated with very low doses is at odds with the long-standing radiation protection recommendations that established these principles in the first place. Notably, as far back as 1977, the ICRP observed that in the choice of alternative practices, radiation risk estimates should be used only with great caution and with explicit recognition of the possibility that the actual risk at low doses may be lower than that implied by a deliberately cautious assumption of linear proportionality of risk with dose.

As observed in E.O. 14300, the ALARA principle as used in the NRC's regulations has lost its intended focus on reasonableness. Instead, as a practical matter, its unbalanced application may very well contribute to more societal harm than the potential harm from the extremely low levels of radiation typical of NRC-licensed activities by hindering the consideration of nuclear technology for energy production and other uses. Therefore, while the NRC recognizes that there is insufficient evidence to refute the use of the LNT model when considering the stochastic health effects of radiation exposure, it also recognizes that the NRC's implementation of the ALARA principle as part of its use of the LNT model—in particular, the nonthreshold aspect of the model—has led to regulatory burden that is not commensurate with the resulting public health and safety benefit and that is not consistent with the original intent of the ALARA principle.

In light of the foregoing, one purpose of this rulemaking is to restore to the NRC's regulations the original intent of the ALARA principle, which is to ensure that dose reductions below the dose limits are only required to the extent that they are reasonable and are supportive of compliance with those dose limits. The NRC proposes to do this

by retiring the use of ALARA terminology in the NRC's regulations; utilizing selected aspects of the linear dose response model in favor of a strict adherence to the LNT model and its emphasis on the lack of a threshold for stochastic effects; and defining required dose management practices below dose limits, which will enable clearer and more objective decision-making regarding dose situations typical of NRC-licensed activities. Stated another way, the NRC proposes to continue to use the linear dose response model, as it continues to be the most appropriate model upon which to base a radiation protection framework; however, the NRC proposes to also detail how licensees should apply a graded approach to dose management to ensure clarity in how doses below the dose limits are to be controlled.

Through this rulemaking, the NRC proposes a complete discontinuation of the use of ALARA terminology in its regulations and guidance. The NRC has concluded that simply issuing a clarification of the intent of the ALARA principle would not be effective in achieving an enduring resolution of the issues associated with the NRC's current implementation of the ALARA principle. As previously discussed, the NRC's current implementation of the ALARA principle allows for excessive subjectivity in the expectations for dose reduction measures, oftentimes resulting in overly conservative outcomes. The proposed rule changes seek to minimize the subjectivity associated with radiation safety decision-making at the low doses typical of NRC-licensed activities. However, these rule changes will not require any changes to licensees' current practices; instead, the rule changes would clarify what is required for compliance but would not preclude licensees from choosing to do more. Therefore, in addition to providing dose limits that are sufficient for the adequate protection of workers and the public, the NRC's regulations would include requirements that are triggered at dose levels below those dose limits to ensure that the dose limits are not exceeded and that radiological hazards are adequately surveyed and controlled. These dose levels would

be the basis for a graded approach to dose management.

With the recognition that the NRC's radiation protection regulatory framework is conservative as described previously, the NRC intends as an additional purpose of this proposed rulemaking to provide additional flexibility and to remove from its regulations overly cautious requirements pertaining to radiological matters. Combined with the proposed retirement of the term ALARA, the proposed changes that would enable licensee flexibility would support the NRC's mission statement by enabling the development of nuclear energy in the United States while maintaining reasonable assurance of adequate protection.

For example, the NRC proposes to reduce certain reporting requirements for radiological monitoring and certain exposure situations in excess of limits. Additionally, the NRC proposes to allow licensees to use dosimetry methods that differ from the systems that serve as the basis for certain provisions in the regulations without needing an approved exemption from those regulations. This proposed change would allow licensees to use modern approaches to dosimetry without incurring the burden and costs of an exemption request.

As it relates to public dose limits, the proposed changes would allow applicants and licensees to apply for higher limits for members of the public who enter the controlled area of a facility and to apply for higher limits for members of the public at large. The controlled area of a facility is defined in 10 CFR 20.1003 as "an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason." In essence, the controlled area is land that a licensee (or applicant) owns or leases (or will own or lease during the period of the license) and thus where it can legally control occupancy and impose other radiation protection measures, as necessary. Regarding occupational dose limits, the proposed changes would allow licensees to manage occupational doses using a multi-year average dose within

acceptable limits without having to implement burdensome provisions associated with planned special exposures when managing the dose limits on an annual basis alone. And, again, these proposed changes would not affect current licensees that desire to continue using their existing practices. These proposed changes are described in greater detail in Section IV.

In accordance with accepted practice in the field of radiation protection, the NRC would continue to emphasize the fundamental radiation protection principles of justification, limitation, and optimization as the guideposts within its radiation protection regulatory framework. However, consistent with International Atomic Energy Agency (IAEA) General Safety Requirements Part 3 (GSR Part 3), "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards"—which provides internationally accepted standards to ensure the protection of people and the environment—under the revisions proposed by this rule, compliance with the NRC's regulations would be taken as evidence of the application of those principles in the United States. Specifically, the principle of justification—ensuring that decisions resulting in radiation exposure do more good than harm—is satisfied by the NRC's enacting legislation, NRC regulations, and the licensing process, which ensures that licensed activities are conducted for the general welfare of the American public as authorized by law. The principle of limitation—the regulatory body establishing and enforcing dose limits—is satisfied by the dose limits in the radiation protection standards reflected in the NRC's regulations. These limits continue to be sufficient to provide reasonable assurance of adequate protection of the public health and safety and the graded approach to dose management requirement proposed in this rulemaking ensures that these limits are not exceeded. The principle of optimization—the process for ensuring that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal, and environmental factors

taken into account—is satisfied by licensees complying with the precautionary requirements in the NRC's regulations, and, as applicable, applying prescribed practices when doses are below regulatory limits to maintain doses within those limits. To minimize subjectivity in implementing the principle of optimization and to avoid the overly cautious practices that resulted from the NRC's previous use of the term ALARA throughout its regulations and guidance, the NRC proposes to provide implementation guidance for a graded approach to dose management below regulatory limits. This approach would ensure that the risk of stochastic effects is adequately controlled by ensuring that regulatory dose limits are not exceeded.

In sum, with this rulemaking, the NRC proposes to use the linear dose response model as a partial basis for its regulations and guidance but would remove from its practices the excessive conservatisms and potential for disproportionate enforcement that result from the LNT model and its emphasis on the lack of a threshold for stochastic effects. This is consistent with the NRC's continued determination that the dose limits are sufficient to provide reasonable assurance of adequate protection of the public health and safety.

Consideration of Determinate Dose Limits

As part of its response to E.O. 14300 section 5(b), the NRC considered whether to propose shifting its radiation protection regulatory framework to be based on a set of determinate dose limits. Determinate dose limits currently exist in the NRC's regulations for nonstochastic effects (tissue effects) because research has revealed that these effects do not occur below a threshold dose value. Thus, a regulatory dose limit can be derived from this threshold dose value by adding margin to the threshold value, and there would be high confidence that no health effects would occur should doses remain within that limit. Such is the case, for example, with the skin dose limit in 10 CFR 20.1201(a)(2)(ii).

Theoretically, a radiation protection regulatory framework based on determinate limits, for both nonstochastic and stochastic effects, could essentially apply a “go/no-go” regulatory approach that would deemphasize radiation protection precautions in lieu of verifications that a licensee is maintaining dose values below the applicable dose limit. In order to move to such a regulatory framework, a basis would be required to establish determinate dose limits for stochastic health effects.

At present, there is no scientific consensus establishing a threshold below which stochastic health effects do not occur. As described in SECY-12-0064, as it relates to stochastic effects, “It is unlikely there might be a threshold level of exposure below which biological response does not occur. Such a threshold could only occur if DNA repair processes were totally effective in that dose range or if a single radiation track were unable to produce an effect. The cellular processes such as apoptosis and cellular differentiation that can protect against later phases of tumorigenesis are judged to be efficient but can be bypassed; there is no reason to believe that those defenses act differently on spontaneous and radiation-induced tumors or have specific dose dependencies.”

Additionally, more recent analysis of datasets focusing on lower doses levels (i.e., 10 rem or less) in “Issues in Interpreting Epidemiologic Studies of Populations Exposed to Low-Dose, High-Energy Photon Radiation” (2020), concludes that the totality of scientific evidence suggests that even if a threshold for stochastic health effects existed it would not be higher than 1 rem, which is significantly below the current occupational dose limit of 5 rem per year for stochastic health effects. Such analyses reflect the evolving understanding of stochastic health effects and indicate challenges with establishing a defensible determinate threshold for these types of effects.

Furthermore, as described in ICRP Publication 103 and supporting publications such as ICRP Publication 118, “ICRP Statement on Tissue Reactions / Early and Late

Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context," there is growing evidence that other health effects such as cataracts may show stochastic behavior, or that the threshold for the effect, if one exists, is lower than originally understood. Therefore, the NRC, after consideration of the available information, concludes that establishing a determinate regulatory dose limit for both stochastic and nonstochastic health effects and adopting a corresponding "go/no-go" regulatory approach is not currently supported by scientific evidence.

Accordingly, the NRC reaffirms its position that the linear dose response model is the most appropriate available consensus model for formulating radiation protection standards and planning radiation protection programs. However, to address deficiencies in the implementation of that model in its current radiation protection regulatory framework, the NRC proposes to provide clarity and increased objectivity to radiation protection decisions by identifying a series of threshold doses that guide actions below the stochastic dose limits. This graded approach to dose management below stochastic dose limits is aligned with the NRC's overall risk-informed approach to regulation. The general purpose of this approach is to ensure that the NRC's radiation protection regulatory framework remains in harmony with scientific consensus while being responsive to the observations in E.O. 14300 regarding the deficiencies associated with the LNT model and the implementation of the ALARA principle in the United States. The graded approach to dose management is described further in Section IV.

Summary of NRC Response to E.O. 14300 Section 5(b)

In summary, as directed by E.O. 14300 section 5(b), the NRC is reconsidering its use of the LNT model and its use of the ALARA principle. The NRC recognizes that there are limitations to the accuracy of the LNT model at very low doses, however, the NRC has also not identified a suitable alternative model. Nevertheless, it may be

possible to improve how the NRC addresses the inherent limitations of the LNT model. Therefore, the NRC is proposing changes to how the LNT model is implemented in its regulations and guidance. These changes, as proposed in this rulemaking, are intended to minimize subjectivity regarding radiation protection at low doses and to make sure that the required management of dose below regulatory dose limits is subject to a more objective reasonableness standard.

Additionally, the NRC considered the use of determinate dose limits for stochastic health effects and determined that the scientific understanding of stochastic health effects does not support the establishment of such limits at this time. Instead, consistent with the original intent of the ALARA principle, the changes proposed in this rulemaking would adopt a graded approach to dose management by identifying a series of dose-based levels that would guide radiation protection decisions below regulatory dose limits.

Further, the NRC is proposing several changes to its regulations to enable flexibility and to remove overly cautious requirements, which would support the E.O. 14300 objective of enabling the development of nuclear energy in the United States while maintaining reasonable assurance of adequate protection. The changes proposed as part of this rulemaking would apply regulatory experience and licensee feedback on operational challenges to address key deficiencies in the application of the NRC's current radiation protection standards, while remaining consistent with the current scientific understanding of the health effects of radiation exposure. These changes would represent a rebaselining of applicable regulations and guidance to reduce the subjectivity that has developed over time in the implementation of the NRC's radiation protection standards with the intent of achieving the original aims of the ALARA principle; specifically, ensuring that the management of dose below applicable dose limits is subject to an objective reasonableness standard that uses sound radiation

protection principles.

Should these changes be implemented, the NRC determined that prior licensing decisions—including environmental reviews, license amendments, and approvals—that involved ALARA would remain valid because of their inherently conservative nature (i.e., because of the prior implementation of the ALARA principle, they would be at least as protective as the proposed revised regulations). This is true because compliance with regulatory dose limits is sufficient to provide reasonable assurance of adequate protection for individuals and ALARA practices seek to establish reasonable margin to the limits and limit the overall risk of health effects that are stochastic in nature. Moreover, the proposed regulatory changes define what is reasonable in order to remove subjectivity on the part of licensees—so if licensees had come to these conclusions on their own, the NRC could have accepted their approaches as being commensurate with the ALARA principle at the time.

Additionally, the proposed changes are designed such that existing radiation protection programs that are compliant with the current requirements would be compliant with the proposed new requirements. Accordingly, the proposed changes would not affect current licensees that desire to continue using their existing programs.

Finally, the NRC determined that the proposed changes would maintain a radiation protection regulatory framework that is in harmony with the United States' commitments to the international community. For example, both Article 15 of the Convention on Nuclear Safety (CNS) and GSR Part 3, which serves as a standard for how countries can meet their obligations under the CNS, include the ALARA principle, with the latter discussing ALARA in its description of the concept of optimization. The graded approach to dose management proposed in this rulemaking meets the description of optimization in Requirement 11 of GSR Part 3 and, therefore, also satisfies CNS Article 15. As explained in this rulemaking, the NRC is proposing to

remove references to the ALARA principle in its regulations and guidance in order to definitively move away from overly conservative practices that have developed over time in the name of ALARA and, through strictly applying the concept of optimization, return to the original intent of the ALARA principle.

IV. Discussion

Description of Proposed Changes to the Regulations

Definitions

The NRC is proposing to remove the definition of “ALARA” because that term would no longer be used within the NRC’s radiation protection regulatory framework. In its place, the proposed rule would add the term “graded approach to dose management.” This term would be defined as an approach whereby progressively increasing radiation protection measures are required as prospective, or actual, radiation doses exceed determinate dose thresholds to provide reasonable assurance that the applicable regulatory limit is not exceeded. This definition reflects the NRC’s determination that its regulatory dose limits are sufficient to provide reasonable assurance of adequate protection of the public health and safety and that the proposed graded approach to dose management requirement ensures that these limits are not exceeded.

The graded approach to dose management serves the purpose of ensuring that dose limits are not exceeded in large part by relying on existing precautionary regulatory requirements (e.g., radiation worker training, radiological monitoring, signage and posting) to control doses below the limits. Additionally, the graded approach to dose management entails that as doses increase and become closer to the dose limits (i.e., at specified determinate thresholds), increasingly more rigorous radiation protection measures would be required to ensure that the dose limits are not exceeded. NRC

guidance would provide one acceptable means for establishing a graded approach to dose management, including appropriate determinate thresholds and corresponding radiation protection measures (e.g., shielding, additional work planning) that are considered reasonable for the circumstances.

As discussed further in this document, the NRC is also proposing to allow the use of alternative dosimetry methods as reflected in new proposed sections of its regulations, specifically, 10 CFR 20.1010 and the associated Appendix H to 10 CFR part 20. This change necessitates that several clarifying statements be added to the definitions section of 10 CFR part 20 (e.g., to the definition of airborne radioactivity area) and to other applicable sections of part 20 to account for the potential that a licensee might use alternative methods and/or alternative derived operational values such as annual limits on intakes, labeling criteria, and derived air concentrations.

Additionally, the term “dosimetry method (or system)” and its definition is proposed to be added as described later in this section. With the proposed allowance of alternative dosimetry methods, the NRC determined that it would also be necessary to provide definitions for certain terms related to dosimetry concepts that have been introduced as part of modern methodologies (e.g., ICRP Publication 60). Therefore, the terms “committed effective dose”, “committed equivalent dose”, “effective dose”, “equivalent dose”, “radiation weighting factor”, and “total effective dose” and their definitions are proposed to be added to 10 CFR 20.1003.

A key difference between the dosimetry methods currently incorporated in the NRC’s regulations and the newer, alternative dosimetry methods proposed to be allowed as part of this rulemaking involves a distinction between the quality factor and the radiation weighting factor. In using a radiation weighting factor to convert from an absorbed dose to an equivalent dose, the newer, alternative dosimetry methods more accurately capture the health effect on entire organs versus at a single point in the organ

as is done when the quality factor is used to develop dose equivalent. Therefore, while the dosimetry methods currently incorporated in the NRC's regulations remain acceptable, the NRC is proposing to include the potential for licensees to use newer, alternative dosimetry methods.

The definitions for the terms "nonstochastic effect" and "stochastic effect" are proposed to be revised to reflect updated scientific understanding and to align the NRC definition with the Department of Energy (DOE) definition, respectively. The definition for the term "nonstochastic effect" would be amended to include the alternative term "tissue effect" to reflect modern terminology and to delete cataracts as an example of the effect in consideration of recent research that indicates that this health effect may be stochastic in nature. The definition for the term "stochastic effect" would be amended to be consistent with the DOE definition for the term in 10 CFR 835.2, which, in turn, closely matches the definition in ICRP Publication 103.

Additionally, the definition for the term "Quarter" is proposed to be revised to correct a typo; the word "consecutive" in this definition is currently misspelled.

Units of radiation dose

The NRC is proposing to add language to § 20.1004 to account for the potential that, with the proposed addition of the option to use alternative dosimetry methods, licensees and applicants may determine values of equivalent dose/dose equivalent and total effective dose equivalent/total effective dose and effective dose equivalent/effective dose using different dosimetry systems. As stated in paragraph 31 of ICRP Publication 60:

> It is appropriate to treat as additive the weighted quantities used by the [ICRP] but assessed at different times, despite the use of different values of weighting factors. The [ICRP] does not recommend that any attempt be made to correct earlier values. It is also appropriate to add values of dose equivalent to equivalent dose and values of effective dose equivalent to effective dose without any adjustments. If values of weighting factors other than those recommended by the [ICRP] are used, this fact should

> be clearly stated, and the values should be explicitly given when the quantities are introduced. These weighted quantities should not be added to the [ICRP's] quantities.

The proposed new § 20.1004(e)(3) would address the possibility that a licensee or applicant may apply a custom dosimetry system with the approval of the NRC, which would be required to include provisions, and supporting justification, for tracking dosimetric quantities similar to the approach that is described in paragraph 31 of ICRP Publication 60.

Alternative dosimetry methods

The proposed rulemaking would define the term "dosimetry method (or system)" as "an approach for calculating the biological effects of ionizing radiation exposure in humans. The approach provides a repeatable method of converting from fundamental knowledge of radioactive decay to biological effects, typically through modeling and a series of conversion and correction factors for types of radiation emitted and interactions with tissues, organs, and the environment." Dosimetry methods are essential to radiation protection because they provide the tools necessary to translate how the physical phenomenon of the energy imparted by radioactive decay results in an impact and potential hazard to public health and safety.

The current radiation protection standards in 10 CFR part 20 use dosimetry methods that are based, with some exceptions, on ICRP Publication 26 (and supporting publications like ICRP Publication 30), which contains the 1977 recommendations of the ICRP. Other NRC regulations and certain license conditions make use of different dosimetry methods. For example, the requirements for technical specifications regarding effluents from nuclear power reactors at 10 CFR 50.36a apply dosimetry methods established in ICRP Publication 1. Additionally, some licensees have applied for NRC approval to use derived limits that are based on more recent dosimetry methods, in particular with respect to internal dose calculations of inhaled radionuclides. The NRC

has approved the use of those methods on a case-by-case basis, concluding that their use provides reasonable assurance of adequate protection of the health and safety of workers and the public and complies with applicable regulatory requirements.

Through a proposed new regulation and a proposed new associated appendix, § 20.1010 and Appendix H to 10 CFR part 20, respectively, the proposed rulemaking would give licensees and applicants the option to voluntarily use specific, alternative, dosimetry methods, without requiring a separate, case-by-case NRC review and approval, to demonstrate compliance with the NRC's radiation protection standards in 10 CFR part 20.

The NRC determined that allowing the use of alternative dosimetry methods based on specific, identified publications would offer flexibility to licensees and applicants, increase efficiency in licensing, operations, and the administration of radiation protection programs, and bring the NRC's radiation protection regulatory framework more in line with current recommendations, while maintaining reasonable assurance of adequate protection of the public health and safety. The NRC determined that this change would maintain the effectiveness of its radiation protection regulatory framework because the specific, alternative, dosimetry methods that would be preapproved for use are appropriate for the scope of activities subject to 10 CFR part 20, are technically adequate and have been published by expert, standards-setting organizations, and provide sufficient transparency regarding associated assumptions and uncertainties. The use of dosimetry methods other than these specific methods would still require case-by-case review and approval by the NRC, and acceptability criteria for requests to use such methods are proposed to be added to the NRC's regulations to streamline that process.

To these ends, the proposed new regulation, § 20.1010, would reference a listing of generically approved alternative dosimetry methods in a proposed new Appendix H to

10 CFR part 20, and it would also provide the criteria for the NRC's approval of a method that is not listed in Appendix H. The methods proposed for inclusion in Appendix H have been promulgated primarily by the ICRP, but the listing of generically approved methods would also include methods published by other consensus-setting organizations. Finally, Appendix H would list the conditions, if any, on the use of these generically approved methods. In the future, the NRC expects to update Appendix H as appropriate, including as more methods become available.

The application of alternative dosimetry methods should be described and controlled within a licensee's radiation protection program, as is required by the existing regulation at § 20.2102, such that dose assessments can be evaluated and, if necessary, reconstructed by a knowledgeable third-party (e.g., NRC inspector). These programs should ensure that dosimetric quantities are determined in accordance with relevant standards and, once determined, are summed in accordance with the proposed regulation at § 20.1004(e)(3).

Documents Incorporated by Reference for Proposed § 20.1010 and Appendix H to 10 CFR Part 20

Reasonable availability of documents—As part of this rulemaking, the NRC is proposing to incorporate by reference (IBR) documents from the American National Standards Institute/American Nuclear Society (ANSI/ANS) and the International Commission on Radiological Protection (ICRP). Upon approval from the Office of the Federal Register, the documents will be available for inspection at the NRC and at the National Archives Records Administration (NARA). Contact the NRC at NRC Technical Library, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301–415–7000; email: *Library.Resource@nrc.gov*. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*. Material from ANSI/ANS is available for

purchase from the ANSI website: https://webstore.ansi.org/. Material from the ICRP is available to the public for free viewing online at the ICRP publication website: https://www.icrp.org/page.asp?id=5.

IBR Summaries—The NRC is proposing to IBR the following documents into proposed Appendix H to 10 CFR part 20 for use as preapproved alternative dosimetry methods per proposed § 20.1010:

ANSI/ANS, 2020. Photon and Neutron Fluence-to-Dose Conversion Coefficients. ANSI/ANS-6.1.1-2020. La Grange Park, IL: American Nuclear Society—ANSI-ANS 6.1.1-2020 (reaffirmed 2025) provides coefficients for converting photon and neutron particle fluence to effective dose based on ICRP Publication 116 data. Separate data are used for cranial and caudal irradiation geometries. Effective dose conversion coefficients are provided in tabular form for incident monoenergetic photons having energies from 10 keV to 10 GeV and for neutrons with energies from 0.001 eV to 10 GeV. Finally, an analytical model is provided for evaluating exposures to both photon and neutron fields in the form of a fourth order polynomial with tabulated numerical coefficients corresponding to exposure geometry and energy.

ICRP, 1990. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1. ICRP Publication 56. Ann. ICRP 20 (2)—ICRP Publication 56 provides an analytical framework for calculating age-dependent committed dose equivalents and effective dose equivalents to members of the public from ingestion and inhalation of radionuclides. The framework incorporates biokinetic and dosimetric models that account for physiological differences from infancy through adulthood and applies the dose calculation methods consistent with ICRP Publications 26 and 30. This report provides organ-specific dose coefficients for 18 radionuclides across six age groups (3 months, 1, 5, 10, and 15 years, and adult) using age-specific anatomical data (e.g., organ masses, bone surface areas) and biokinetic parameters (e.g.,

gastrointestinal absorption fractions, retention half-times, tissue distribution). ICRP Publication 56 is the first in a series of five reports that also includes ICRP Publications 67, 69, 71, and 72 that provides radionuclide-specific, age-dependent, dose coefficients for members of the public.

ICRP, 1993. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients. ICRP Publication 67. Ann. ICRP 23 (3-4)—ICRP Publication 67 is part two of a series of five reports (i.e., ICRP Publications 56, 67, 69, 71, and 72) that provides radionuclide-specific, age-dependent, ingestion and inhalation dose coefficients for members of the public. This report provides ingestion dose coefficients for 13 radionuclides using the framework described in ICRP Publication 56, but with tissue weighting factors from ICRP Publication 60. Additionally, the report updates age-specific, biokinetic models for the alkaline earth elements, lead, and selected transuranic radionuclides for incorporation of ICRP Publication 60 tissue weighting factors and methods and updated understanding of human biokinetics, as applicable. Lastly, the report provides recalculated ingestion dose coefficients for the radioisotopes covered by ICRP Publication 56 using the ICRP Publication 60 tissue weighting factors and methods.

ICRP, 1994. Dose Coefficients for Intakes of Radionuclides by Workers. ICRP Publication 68. Ann. ICRP 24 (4)—ICRP Publication 68 provides dose coefficients for occupational intakes—inhalation and ingestion—of radionuclides, that applied the tissue and radiation weighting factors from ICRP Publication 60. The report incorporates the revised Human Respiratory Tract Model from ICRP Publication 66 and updated systemic biokinetic models in ICRP Publications 56 and 67. Additionally, the report addresses excretion pathways, gastrointestinal tract modeling, and provides effective dose rates for inert gases and soluble/reactive vapors.

ICRP, 1995. Age-dependent Doses to Members of the Public from Intake of

Radionuclides - Part 3 Ingestion Dose Coefficients. ICRP Publication 69. Ann. ICRP 25 (1)—ICRP Publication 69 is part three of a series of five reports (i.e., ICRP Publications 56, 67, 69, 71, and 72) that provides radionuclide-specific, age-dependent, ingestion and inhalation dose coefficients for members of the public. This report provides ingestion dose coefficients for five radionuclides not covered in ICRP Publication 67.

ICRP, 1995. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients. ICRP Publication 71. Ann. ICRP 25 (3-4)—ICRP Publication 71 is part four of a series of five reports (i.e., ICRP Publications 56, 67, 69, 71, and 72) that provides radionuclide-specific, age-dependent, ingestion and inhalation dose coefficients for members of the public. This report provides inhalation dose coefficients for the radionuclides covered in ICRP Publications 56, 67, and 69 and for calcium and curium. Additionally, the report provides biokinetic models for calcium, curium, and decay products for selected radionuclides. Finally, the report provides an approach for determining absorption types in cases where material-specific, absorption type is not known.

ICRP, 1995. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients. ICRP Publication 72. Ann. ICRP 26 (1)—ICRP Publication 72 is part five of a series of five reports (i.e., ICRP Publications 56, 67, 69, 71, and 72) that provides radionuclide-specific, age-dependent, ingestion and inhalation dose coefficients for members of the public. This report provides a compilation of age-dependent committed effective dose coefficients for members of the public from intakes by ingestion and inhalation of the 31 elements covered in ICRP Publications 56, 67, 69, and 71, as well as for the 60 elements covered in ICRP Publication 68 for workers.

ICRP, 2010. Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures. ICRP Publication 116. Ann. ICRP 40(2–5)—ICRP

Publication 116 provides fluence-to-dose conversion coefficients for effective dose and organ absorbed doses from external radiation exposures, based on ICRP Publication 103 recommendations and using official computational phantoms representing the Reference Adult Male and Reference Adult Female. The report covers a broad range of radiation types and various irradiation geometries and includes coefficients for organ-specific doses, eye lens, skin, and skeletal tissues. The report includes annexes with extensive tabulated coefficients, dose–response functions, and guidance for aircraft crew dosimetry.

ICRP, 2015. Occupational Intakes of Radionuclides: Part 1. ICRP Publication 130. Ann. ICRP 44(2)—ICRP Publication 130 provides an introduction to a series of reports that include information for calculating doses from occupational intakes of radionuclides. This report includes sections on control of occupational exposures, biokinetic models (including a revision to the human respiratory tract model that was published in ICRP Publication 66), dosimetric models, monitoring methods and programs, and general aspects of retrospective dose assessment. ICRP Publication 130 is part one of a series of five reports that also includes ICRP Publications 134, 137, 141, and 151 that provides dose coefficients for occupational intakes of radionuclides by inhalation and ingestion. This information in this series of reports was meant to replace the dose coefficients for occupational dose calculations found in ICRP Publications 30 and 68 by implementing the ICRP's recommendations in ICRP Publication 103.

ICRP, 2016. Occupational Intakes of Radionuclides: Part 2. ICRP Publication 134. Ann. ICRP 45(3/4), 1–352—ICRP Publication 134 is part two of a series of five reports (i.e., ICRP Publications 130, 134, 137, 141, and 151) that provides dose coefficients for occupational intakes of radionuclides by inhalation and ingestion. As part of this report series, the ICRP published an electronic database (available at https://www.icrp.org/) that contains a comprehensive set of committed effective and

equivalent dose coefficients, committed effective dose per content functions, and reference bioassay functions that apply to scenarios involving inhalation, ingestion, and direct input to blood. This report provides data on several individual elements and their radioisotopes, including information on chemical forms encountered in an occupational setting, decay information, and reference parameter values for input into biokinetic models. Additionally, this report provides several corrections that are applicable to ICRP Publication 130.

ICRP, 2017. Occupational Intakes of Radionuclides: Part 3. ICRP Publication 137. Ann. ICRP 46(3/4)—ICRP Publication 137 is part three of a series of five reports (i.e., ICRP Publications 130, 134, 137, 141, and 151) that provides dose coefficients for occupational intakes of radionuclides by inhalation and ingestion. As part of this report series, the ICRP published an electronic database that contains a comprehensive set of committed effective and equivalent dose coefficients, committed effective dose per content functions, and reference bioassay functions that apply to scenarios involving inhalation, ingestion, and direct input to blood. This report provides data on several individual elements and their radioisotopes, including information on chemical forms encountered in an occupational setting, decay information, and reference parameter values for input into biokinetic models. Additionally, this report provides background information for dosimetry of radon progeny and dose coefficients in the electronic database referenced above.

ICRP, 2019. Occupational Intakes of Radionuclides: Part 4. ICRP Publication 141. Ann. ICRP 48(2/3)—ICRP Publication 141 is part four of a series of five reports (i.e., ICRP Publications 130, 134, 137, 141, and 151) that provides dose coefficients for occupational intakes of radionuclides by inhalation and ingestion. As part of this report series, the ICRP published an electronic database that contains a comprehensive set of committed effective and equivalent dose coefficients, committed effective dose per

content functions, and reference bioassay functions that apply to scenarios involving inhalation, ingestion, and direct input to blood. This report provides data on several individual elements and their radioisotopes, including information on chemical forms encountered in an occupational setting, decay information, and reference parameter values for input into biokinetic models. Additionally, this report provides several corrections that are applicable to ICRP Publication 137.

ICRP, 2020. Dose Coefficients for External Exposures to Environmental Sources. ICRP Publication 144. Ann. ICRP 49(2)—ICRP Publication 144 provides the technical basis for the calculation of external dose-rate coefficients for environmental exposure of members of the public, as well as a tabulation of coefficients. The calculations include modeling of environmental radiation fields, computation of organ and effective dose-rate coefficients for exposures to monoenergetic photons and electrons, and the use of these data to calculate dose-rate coefficients. The report provides tables of dose-rate coefficients for selected radionuclides for use in determining external doses from submersion in water, submersion in air (1 meter above ground), and for radionuclides distributed at a depth of 0.5 g/cm^2 in soil. The supplementary material that accompanies the report provides external dose-rate coefficients for 1,252 radionuclides of the 97 elements whose decay information is provided in ICRP Publication 107. Additionally, this report provides dosimetry information for the skeleton and the skin.

ICRP, 2022. Occupational Intakes of Radionuclides: Part 5. ICRP Publication 151. Ann. ICRP 51(1–2)—ICRP Publication 151 is part five of a series of five reports (i.e., ICRP Publications 130, 134, 137, 141, and 151) that provides dose coefficients for occupational intakes of radionuclides by inhalation and ingestion. As part of this report series, the ICRP published an electronic database that contains a comprehensive set of committed effective and equivalent dose coefficients, committed effective dose per content functions, and reference bioassay functions that apply to scenarios involving

inhalation, ingestion, and direct input to blood. This report provides data on several individual elements and their radioisotopes, including information on chemical forms encountered in an occupational setting, decay information, and reference parameter values for input into biokinetic models. Additionally, this report provides effective dose rate coefficients for several radionuclides that apply to the submersion exposure pathway of occupationally exposed individuals, and it provides a description of how the contribution to dose from progeny is accounted for in this series of reports.

References to the ALARA principle

As part of this rulemaking, the NRC is proposing to remove references to the ALARA principle from its regulations and guidance. While the implementation of the ALARA principle based on the NRC's current regulatory language has generally led to low overall radiation doses, over time it has also resulted in overly cautious dose reduction efforts beyond what are reasonable and lacking clear alignment with actual risk or benefit. As E.O. 14300 observes, implementing the ALARA principle in this manner has resulted in over-conservatism likely to the detriment of nuclear technology development because it leads to an overemphasis on the reduction of risks that the state-of-knowledge identifies as being minimal. The ALARA principle has also been superseded by the concept of optimization in the system of radiation protection recommended by the ICRP. As discussed previously in this document, in response to E.O. 14300, the NRC reconsidered the use of the ALARA principle in its regulations and determined that in order to return to the original intent of the ALARA principle and to align with the more recent concept of optimization, the appropriate approach would be to replace the ALARA principle with a requirement for a graded approach to dose management. To this end, the NRC proposes to remove all instances of the term ALARA from its regulations and to specify that the original intent of the ALARA principle will be

achieved through the use of a new graded approach to dose management.

The concept of optimization is defined in the 2022 IAEA Nuclear Safety and Security Glossary as, “The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account (ALARA).” Requirement 11 of the IAEA’s GSR-3 states that, “The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized.” Further details regarding the regulatory body’s responsibilities pertaining to optimization include establishing requirements for optimization, requiring documentation addressing optimization, and the administration of constraints (or thresholds) on dose, or risk, as appropriate. The 2022 IAEA Nuclear Safety and Security Glossary describes the purpose of constraints as boundaries in defining the range of options in optimization.

As discussed previously in this notice, in order to address the problems of subjectivity and over-conservatism that were introduced over time through the implementation of the references to the ALARA principle throughout the NRC’s regulations, the NRC proposes removing these references and replacing them with a requirement for a graded approach to dose management, which would essentially be an application of the concept of optimization that, below the dose limits, relies on various existing regulatory requirements as well as licensees’ individual radiation protection programs to manage dose. NRC guidance would provide an acceptable approach for this. The graded approach to dose management would rely on a series of threshold doses below the regulatory dose limits and dose management actions to be taken at each threshold dose. These threshold doses and dose management actions would

generally correspond to existing requirements in 10 CFR part 20 or other regulations and, therefore, should already be incorporated within the radiation protection programs of existing licensees to a degree “commensurate with the scope and extent of licensed activities” as is currently required by § 20.1101.

For any occupational exposure scenario, compliance with 10 CFR part 20 would provide both optimization and reasonable assurance of adequate protection from radiation exposure up to and including planned special exposure events and the proposed planned occupational dose limit extensions. For example, licensees are required to conduct surveys, control access to certain areas, store material appropriately, and use signs, postings, and labels to warn workers of radiological hazards. These provisions are in effect for the full spectrum of radiological hazards that a licensee could encounter during the course of its licensed activities, and thus, these provisions form the first set of dose management actions below the regulatory dose limits that would be credited as part of a graded approach to dose management.

Under a graded approach to dose management, additional dose management actions would apply as radiological hazards increase and move closer to the applicable regulatory dose limit. The dose levels corresponding to dose management actions are threshold doses in that they represent determinate boundaries above which a specific action is required and below which they are inapplicable (i.e., there is no subjectivity to when a specific dose management action should be taken). Examples of these progressively increasing, threshold doses for occupational exposure are: expected doses of 100 mrem/year, 500 mrem/year, and 5 rem/year. Specifically, above an expected dose of 100 mrem/year, licensees are required to provide instructions to workers (i.e., radiation worker training) per 10 CFR 19.12; above an expected dose of 500 mrem/year, or, more specifically, 10 percent of the applicable limit, licensees are required to monitor doses to individual workers per 10 CFR 20.1502; and above an

expected dose of 5 rem/year (i.e., the regulatory dose limit), licensees can exercise the proposed new planned occupational dose limit extension of § 20.1205 or the existing planned special exposure process of § 20.1206, if the situation requires higher dose.

The NRC is developing guidance to further explain and provide acceptable approaches for implementing the graded approach to dose management, including alternative radiation protection measures not already set out in the NRC's regulations that would help ensure that dose limits are not exceeded. The NRC's guidance would explain that it would be acceptable for radiation protection measures under the graded approach to dose management to be supported by a comparison of the cost of the radiation protection measure (e.g., shielding, additional workers, robotics) to a reasonably calculated cost-basis of an averted person-rem. The proposed guidance would provide that one example of a reasonable cost-basis standard is provided in NUREG-1530, "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy." Specifically, in that guidance document, the NRC establishes the cost of an averted person-rem by multiplying a value of a statistical life coefficient—a factor that corresponds to society's willingness-to-pay for small reductions in a particular mortality risk—by a cancer mortality risk coefficient. The nominal cost of an averted person-rem under this standard is $5,200 (in 2014 dollars). Taken together, this means that it would be acceptable for considering under the graded approach to dose management whether additional radiation protection measures are reasonable based on a need to spend $5,200 to avoid a person-rem of exposure. Consequently, if a radiation protection measure were more costly than that, the licensee would have an acceptable cost-justified basis for not implementing the measure and instead accruing the dose as long as that dose is within the regulatory dose limits or, if applicable, the licensee complies with the provisions regarding planned occupational dose limit extensions or planned special exposures. In this manner the graded approach to dose management would

maintain occupational dose below the regulatory dose limits while replacing the subjectivity of the current ALARA-based regulations with objective cost-benefit analyses. This guidance would be issued subsequent to this rulemaking as part of the NRC's planned two-phased approach to issuing guidance associated with this rulemaking, see Section VI, "Availability of Guidance," for more information.

As part of this rulemaking, the NRC also proposes to require a graded approach to dose management with respect to public dose in place of the existing implementation of the ALARA principle. The objective is to maintain a layered protective approach to potential public dose as a precautionary measure. Public dose differs from occupational exposure in several key respects. First, the dose to individual members of the public is generally calculated based on an exposure scenario, whereas occupationally exposed individuals are usually monitored. For example, with respect to nuclear power plant effluents, the member of the public is assumed to be a hypothetical maximally exposed individual who represents the maximum exposure regarding food consumption, occupancy, and other usage in the vicinity of the plant site. Another example is that for a waiting room in a medical facility, the facility may conduct area monitoring and assume conservative occupancy of the waiting room. Another difference between public dose and occupational dose is that the dose limit itself is much lower for the public than for occupationally exposed individuals (i.e., 100 mrem/year vs. 5,000 mrem/year, respectively), and the public dose limit represents a very low level of risk. Specifically, as described in Table 12-4 of the BEIR VII report, the average lifetime risk of dying from cancer is 20 percent, and a lifetime (i.e., 70 years) of exposure at the public dose limit of 100 mrem/year would conservatively result in an addition of only 0.35 percent to that average lifetime risk. Importantly, the public dose limit is based on the risk of cancer mortality to a large population that is assumed to be exposed at the full limit for a lifetime. However, as just mentioned in the nuclear power plant effluent and medical

waiting room examples, in practice, licensees calculate bounding doses to smaller subsets of the population and use the parameters in those calculations to control doses (e.g., reducing effluents from power plants or installing shielding around medical equipment). This means that the actual dose to the average member of the public from NRC licensed activities is assuredly below the limit, and thus, that that individual faces an even smaller risk than the already small risk that is assumed by a lifetime of exposure at the limit.

Because of these inherent conservatisms, the NRC would explain in guidance that one acceptable way of managing dose below the public dose limit—which management would be required under the proposed new graded approach to dose management—is to perform cost-benefit analyses using the assumptions of NUREG-1530, or equivalent assumptions, for any doses to members of the public that are projected to be greater than or equal to 25 percent of the public dose limit (i.e., 25 mrem/year). In addition, this approach to managing public dose would also be acceptable because the existing precautions in 10 CFR part 20 (e.g., waste disposal regulations in subpart K) or other regulations intended to limit public dose (e.g., 10 CFR 50.36a) are sufficient to manage doses to the public within the public dose limits as required by § 20.1101. Stated another way, the assumptions in the calculation of public dose and in the public dose limit itself, in combination with already-existing NRC requirements related to dose management, make it so that it is acceptable to comply with the proposed new graded approach to dose management by not analyzing projected public doses below 25 mrem/year and by performing a cost-benefit analysis for projected public doses greater than or equal to 25 mrem/year. This approach would essentially reestablish the original intent of the ALARA principle of minimizing dose below limits to the extent that doing so is reasonably achievable and would ensure that dose limits are not exceeded. Again, as with the implementation of the proposed new

graded approach to dose management for occupational dose, whereas the NRC's proposed guidance provides one way by which a licensee can satisfy that requirement for public dose, licensees may propose other ways to satisfy the requirement.

Effluents

The NRC's regulations include requirements for maintaining control over the release of radioactive material to the environment during normal reactor operations. For example, under § 50.34a and § 50.36a, the NRC requires nuclear power plant licensees to include in their facilities measures to control radiological effluents to the environment—including via monitoring and control systems—and to have in their licenses technical specifications to control the release of effluents. For power reactors, Appendix I to 10 CFR part 50 provides numerical design objectives regarding effluents. These design objectives are translated into performance criteria that are reflected in plant-specific technical specifications. In these requirements, effluents are quantified using the calculated dose that a member of the public would receive when exposed to the effluents under limiting conditions, i.e., the hypothetical maximally exposed individual who represents the maximum exposure regarding food consumption, occupancy, and other usage in the vicinity of the plant site.

A similar requirement regarding air emissions for licensees not subject to § 50.34a and § 50.36a is provided in § 20.1101(d). These requirements were added to the NRC's regulations to provide design objectives and constraints to ensure that radioactive effluents (and thus the resulting public doses) would be maintained consistent with the ALARA principle. Additionally, the NRC has used these types of regulations to meet environmental protection-related obligations under the Clean Air Act (CAA) and to demonstrate compliance with the environmental protection standards for nuclear power operations under 40 CFR part 190. In NUREG-0543, the NRC describes how a licensee would be in compliance with the dose-based requirement in 40 CFR part 190, if the

licensee maintains effluents below the numerical criteria of Appendix I to 10 CFR part 50.

In the context of the CAA, the NRC has historically worked with the U.S. Environmental Protection Agency (EPA) to develop effluent standards that are sufficiently low to support EPA determinations and to ensure that NRC licensees are not subjected to redundant regulation from multiple agencies (see, e.g., 42 FR 2858, 54 FR 51654, and 61 FR 65120). As part of the development of the current air emissions constraint in § 20.1101(d), the NRC ensured that the value of that constraint would be such that the Administrator of the EPA could determine that the constraint provided "ample margin of safety," as is required under Section 112(d)(9) of the CAA. This "ample margin" determination is explained in the proposed and final rules that promulgated the National Emissions Standards for Hazardous Pollutants (NESHAPs) for radionuclides (54 FR 9612 and 54 FR 51654, respectively). EPA supported its determination that the NRC's regulations would satisfy the "ample margin" statutory requirement with studies of air emissions from NRC and Agreement State licensees. In total, these studies considered air emissions from 412 facilities on an annualized basis. EPA found that air emissions from most facilities do not result in doses exceeding 1 mrem/year with a small percentage of facilities approaching, but none exceeding, 10 mrem/year.

As part of its response to E.O. 14300, the NRC reconsidered risk analyses that are based on the LNT model and the implementation of the ALARA principle, as described elsewhere in this proposed rule. As it pertains to doses to members of the public, the NRC maintains that there is reasonable assurance that public health and safety is adequately protected at all doses below the NRC's current regulatory dose limit of 100 mrem/year. Dose reduction below this limit in and of itself is not necessary for ensuring the public health and safety; instead, as clarified by this proposed rulemaking, dose reduction serves the purpose of ensuring that ample margin exists to the regulatory

dose limit and thus ensures that the limit is not exceeded. Regarding the contribution of effluents to public dose, this margin to the dose limit is maintained by the requirements in the NRC's regulations that pertain to the monitoring and control of effluents and by licensees' actions to manage dose, which could include performing cost-benefit analyses to support decision making on additional measures for controlling doses below the dose limits.

Accordingly, the NRC is proposing revisions to radionuclide emissions standards in 10 CFR 50.34a, 10 CFR 50.36a, 10 CFR part 50 Appendix I, and 10 CFR 20.1101(d) because it has determined that they are excessively cautious and overly burdensome. Specifically, the NRC is proposing to increase its radionuclide emissions standards from the current regulatory constraint in 10 CFR 20.1101(d) of 10 mrem per year to 25 mrem per year. The NRC's position is that this would remove excess conservatisms while continuing to provide an adequate basis to EPA that the NRC's regulatory framework provides "ample margin of safety to protect the public health" under section 112(d)(9) of the CAA. To illustrate, in its proposed NESHAP rule for radionuclides, the EPA characterized the maximum lifetime risk of fatal cancer from natural background radiation from all sources, including naturally occurring radon, as approximately $1x10^{-2}$, or 1 case per 100 people. Using a current, widely accepted, and likely conservative cancer risk coefficient of $5x10^{-4}$ per rem (see NCRP 180, Section 4.1), an individual receiving a dose of 10 mrem per year, the current regulatory constraint in 10 CFR 20.1101(d), for 70 years would experience an excess fatal cancer risk of $3.5x10^{-4}$, or about 0.04 cases per 100 people. If the dose to that individual were raised to 25 mrem per year, the proposed new regulatory constraint, for 70 years, the individual would experience an excess fatal cancer risk of $8.7x10^{-4}$, or about 0.09 cases per 100 people. When compared to the baseline lifetime risk of fatal cancer of approximately 0.2 (e.g., as provided in Table 12-4 of the BEIR VII report), or 20 cases per 100 people, the risks of

these environmental levels of radiation exposure, at both 10 mrem per year and 25 mrem per year, are a small fraction and well below the 100 mrem per year public dose limit.

In addition to reconsidering its current radionuclide emissions standards through a risk perspective, the uncertainties associated with risk estimates based on extrapolations from high-dose and high-dose-rate data provide additional support for the NRC's position that its proposed increase to its radionuclide emissions standards would remove excess conservatisms while still providing reasonable assurance of adequate protection of the public health and safety and would also continue to support EPA's determination that the NRC's standards provide an ample margin of safety under the CAA. Adjustments in the slope of the dose response curve, such as is done with the DDREF, are helpful in the extrapolation of high-dose/high-dose-rate data to low doses; however, there is subjectivity and potential conservatism associated with this adjustment. Additionally, there is evidence for adaptive cellular response, which would mitigate the health effects of exposures at low doses, especially those resulting from effluents. The NRC determined that these uncertainties were undervalued in the establishment of the radionuclide emissions standards that the NRC currently uses.

The NRC's proposed approach to the regulation of effluents would involve allowing licensees to continue using the existing effluent constraints of 10 mrem per year or allowing licensees to use a new constraint of 25 mrem per year TEDE or TED, as applicable. Regardless of the constraint used by a licensee, if the licensee demonstrates that its effluents are below the 25 mrem per year level, it would only be required to collect and retain effluent data on an annual basis and in a format that can be inspected by the NRC. If a licensee releases effluents greater than or equal to the 25 mrem per year constraint, that licensee would be required to collect and retain effluent data and submit relevant reports to the NRC on an annual basis until levels are returned to below

the 25 mrem per year constraint. Additionally, such a licensee would be required to evaluate and consider implementing cost-justified corrective actions to restore effluent levels to below the 25 mrem per year constraint. NRC guidance would provide that one acceptable method for performing this evaluation would be to use the dollar per person rem value from NUREG-1530. If a cost analysis demonstrates that corrective actions are not justified, the licensee could propose a new constraint that would support continued operations in a cost-justified manner, but this new constraint would be required to be below the public dose limit. A similar approach would be taken during the licensing of a new facility, i.e., a constraint higher than the regulatory constraint, but lower than the public dose limit, could be proposed as needed to support operations in a cost-justified manner. These changes are being proposed to §§ 20.1101(d), 50.34a, and 50.36a and to appendix I to 10 CFR part 50. To avoid disruptions to existing licensees, the NRC is proposing these changes such that existing effluent programs will remain compliant with the NRC's requirements, as amended, and that licensees can adopt changes on a voluntary basis.

The NRC understands that its radionuclide emissions constraint relates to EPA's ample margin determination under section 112(d)(9) of the CAA. According to CAA section 112(d)(9), the EPA must consult with NRC prior to a new or revised ample margin determination. The NRC's proposed position is that the proposed change to its radionuclide emissions constraint could continue to provide an adequate basis to EPA for such a determination.

Additionally, the NRC is proposing to revise paragraph C of Section IV of Appendix I to 10 CFR part 50 to add "§ 52.110" to the applicability of the provisions in that paragraph. This is an editorial change to make paragraph C consistent with the applicability specified in the introductory paragraph of Section IV.

Planned Occupational Dose Limit Extension

In the NRC's current regulations, planned special exposures (PSEs) (see 10 CFR 20.1206) allow occupationally exposed individuals to receive doses in excess of the applicable limit to a maximum of twice the applicable limit in one year, provided that certain criteria are met (e.g., documentation tracking lifetime dose and remaining bank of PSE-dose). There is a cap on PSE-dose of five times the applicable limit over the lifetime of an individual. To ensure compliance with this lifetime cap, a licensee must ascertain the lifetime exposure history of an individual prior to conducting a PSE of that individual. Additionally, a PSE is viewed as a tool to be used only during exceptional circumstances. As such, PSEs involve additional reporting and recordkeeping requirements when compared to routine occupational exposures. Since the NRC added the regulations allowing for PSEs in the 1991 revisions to 10 CFR part 20, PSEs have not been used by licensees, as demonstrated through a lack of reports having been submitted to the NRC per § 20.2204.

The NRC has determined that the administrative burden associated with PSEs (e.g., determination of lifetime exposure histories and additional reporting requirements) combined with the characterization of a PSE as a tool to be used only in exceptional circumstances is not commensurate with the radiological risk involved with exposures at occupational levels. Additionally, the increased administrative burden associated with PSEs likely dissuades licensees from viewing PSEs as a viable option for occupational dose management. Given this background and to enable flexibility in the balancing of occupational exposure with operational needs, the NRC is proposing to codify in 10 CFR 20.1205 a new process for allowing workers to receive doses in excess of applicable annual limits: the planned occupational dose limit extension (DLE). This optional process would make available to licensees a method to manage a justified, pre-planned exceedance of annual occupational limits for workers, provided that an adequate

decision-making process is applied to support its use and that the overall dose is limited within specified multi-year average values and annual limits are limited to twice the applicable limit. Although the NRC is also maintaining the current PSE process in its regulations, the proposed new planned occupational DLE would be less burdensome for licensees to implement while still maintaining occupational doses, and thus the underlying risk, within acceptable values.

The proposed new planned occupational DLE would allow licensees to access, in the current year, occupational dose that was not given to a worker in previous years. Dose limits generally serve two purposes: (1) to avoid nonstochastic/deterministic effects, also called tissue effects, and (2) to manage stochastic risk to an acceptable level. Nonstochastic/deterministic effects, or tissue reactions, are effects that are only seen once a threshold is exceeded and their severity is dependent upon the dose received. Protraction of dose reduces the risk of nonstochastic/deterministic effects especially at doses below the threshold because the body is able to heal the biological damage resulting from the dose received. Stochastic effects are random in nature; they are not subject to a threshold and the severity of the health effect is independent of the dose received. Currently accepted models assume that for stochastic effects the likelihood/risk of an adverse health effect occurring increases proportionately with dose. Each of the NRC's occupational dose limits functions to limit the risk of adverse health effects associated with radiation exposure to levels that have been determined to be acceptable for routine occupational situations.

Occupationally exposed individuals rarely approach even small fractions of applicable dose limits (see NUREG-0713) because of licensees' existing dose management efforts, which are generally founded on ALARA practices. In general, the fact that the risk from radiation exposure has been made negligible because of these dose management efforts is a net benefit. However, it is likely that these measures have

resulted from overly conservative decision-making. Additionally, some licensees use locally developed administrative limits to maintain margin to occupational dose limits. Occasionally, normally during maintenance periods, licensees may encounter the need for workers to be exposed to doses in excess of annual limits but still within the standards for protecting against the health effects of radiation exposure (e.g., long-term averages with respect to lifetime doses). In these cases, in part to avoid the added burden of PSE use, licensees employ additional measures (e.g., shielding) or use additional workers to spread out the dose so as to maintain individual doses below limits. However, these actions may increase the cost and the time associated with the work in a manner that is not commensurate with the risk associated with the dose.

To encourage more reasonable decision-making regarding doses at levels corresponding to occupational exposures, consistent with the original intent of the ALARA principle and the proposed graded approach to dose management, the NRC is proposing to add to its regulations the planned occupational DLE process to allow licensees to periodically exceed applicable dose limits for an individual worker provided that certain criteria are met. The NRC proposes to define the dose allowed for a planned occupational dose limit extension as the occupational exposure that was unused by the individual over the most recent 5-year period. For example, for the TEDE limit of § 20.1201(a)(1), this would mean the dose available is equal to the product of 5 years and 5 rem TEDE, totaling 25 rem TEDE, minus the actual annual TEDE received by the individual in the current year and the preceding 4 years. A similar approach can be used to determine the allowable dose for a planned occupation dose limit extension of the deterministic limits, with the exception of the lens dose limit. Licensees would be able to apply this allowable dose, or “retrospective dose,” up to a total dose of twice the applicable annual dose limit in the current year. Thus, the annual limit for the planned occupational dose limit extension would be consistent with the dose that is allowed

through the planned special exposure, with the exception of lens dose.

The safety basis for the proposed new planned occupational dose limit extension process relies on the fact that annual dose limits are derived with the intent to limit total lifetime exposure to an individual worker and to preclude deterministic effects. However, because total lifetime exposure is not a practical value to measure, radiation protection standards prescribe annual stochastic limits that are essentially fractionated lifetime totals. Therefore, the annual stochastic limits in and of themselves should not be viewed as demarcations of safety or thresholds above which health effects are expected. Instead, they are regulatory tools to manage the long-term risks of exposure. As such, these limits can safely be exceeded to a certain extent in the short-term, provided that long-term doses continue to be controlled adequately. When an occupationally exposed individual receives an annual dose below the annual limit, that individual is experiencing a smaller risk than was originally assumed to be acceptable for a radiation worker in developing the annual dose limits. In general, this is a positive outcome, primarily because of the corresponding reduction in risk that is associated with reductions in dose inherent to the statistical nature of stochastic effects. However, this also means that there often exists unused retrospective dose that could be safely used, provided that an adequate decision-making process is applied to support its use and that the overall dose is limited within specified multi-year average values. Deterministic effects would not result from the planned occupational dose limit extension process because those effects are only seen when certain thresholds are exceeded, and the restrictions on the planned occupational dose limit extension process would maintain doses below those thresholds.

The proposed new planned occupational dose limit extension process, as described in § 20.1205, would allow a licensee to authorize an individual worker to receive a dose in excess of annual occupational dose limits provided that (1) the licensee does not authorize a dose that would cause the individual to receive twice the

applicable annual dose limit in a year, and (2) sufficient retrospective dose is available to the individual. This process would also entail limitations and reporting and recordkeeping requirements. For example, approval of a planned occupational dose limit extension for an adult worker must be in writing before the exposure occurs; the individual must be informed of the purpose of the planned operation, estimated doses and their associated risks, and measures taken to manage doses; and the licensee must determine the occupational exposure of the individual during the current and preceding four years (see 10 CFR 20.1205). Furthermore, declared pregnant women and minors would not be allowed to participate in planned occupational dose limit extensions. Additionally, because of the uncertainty associated with the health risks of lens dose, as discussed previously in this document, the NRC has decided to exclude exceeding the annual lens dose limit from the proposed new planned occupational dose limit extension process; however, licensees could still use the current PSE process, which will remain in the NRC's regulations (including the required lifetime dose determination), in situations that involve a need to exceed the annual lens dose limit. Finally, the requirement to implement a graded approach to dose management would also apply to the management of the doses received during planned occupational dose limit extensions such that unnecessary occupational exposure would be avoided and radiation protection practices would be employed commensurate with the risks involved.

Public Dose Limits

The NRC is not proposing to change its current public dose limit, which is 100 mrem per year. The NRC considered several recommendations to change the public dose limit. As described previously, the 2015 PRMs requested an increase in the public dose limit based, in part, on the assertion that radiation exposure is beneficial. Additionally, the Idaho National Laboratory—a U.S. National Laboratory dedicated to energy research and development—recently suggested in a public report ("Reevaluation

of Radiation Protection Standards for Workers and the Public Based on Current Scientific Evidence," INL/RPT-25-85463, Revision 0, July 2025) that the public dose limit be raised, in part, to increase public acceptance of radiation exposure.

The NRC regulates the civilian use of radioactive materials in a manner that provides reasonable assurance of adequate protection of the public health and safety. Although the current public dose limit is sufficient to provide reasonable assurance of adequate protection of the public health and safety, the NRC understands that it is a generic limit and, thus, may be overly conservative in certain, specific circumstances. The NRC also recognizes that a number of factors may weigh in favor of allowing a higher public dose limit on a case-by-case basis when such conservatisms are specifically identified and accounted for, including why such an allowance would remain protective of the public health and safety. As discussed previously, in response to E.O. 14300 section 5(b), the NRC reexamined its approach to radiation protection and recognizes that there are inherent limitations in the LNT model, particularly at low doses, that could be better addressed in the NRC's rules. One example is the decision in the NRC's 1991 rulemaking to disallow exceptions to the public dose limit for new applicants. Upon reexamination, such a limitation is not needed for reasonable assurance of adequate protection of public health and safety and is also inconsistent with the principles of the E.O.s discussed in this document concerning enabling the use of nuclear power, particularly in light of the declared energy emergency in E.O. 14156. Taken together, these factors weigh in favor of the NRC reconsidering whether exceptions to the generic public dose limit of 100 mrem per year may be allowed. Therefore, although it is not proposing to change its current public dose limit or define specific exceptions to that limit, the NRC is proposing revisions to the regulations in § 20.1301 that would allow a licensee or an applicant to request alternative public dose limits on a sufficiently supported, case-by-case basis.

First, in § 20.1301(b), the NRC is proposing a path to enable a licensee or applicant to request prior NRC authorization for a public dose limit in excess of 100 mrem per year for members of the public who have access to controlled areas. Such requests may be on a generic basis (e.g. for a design). A controlled area, as defined in § 20.1003, is an area, outside of a restricted area but inside the site boundary, to which access can be limited by the licensee for any reason. The NRC's current regulations extend the public dose limit to all areas within the site boundary. However, this approach may be excessively restrictive if dose is appropriately managed in the controlled areas. This is because members of the public do not maintain a lifetime of continuous occupancy in spaces within the controlled area boundary of licensed facilities. Instead, members of the public typically access these spaces on a temporary basis for such non-occupational-exposure purposes as tours, awaiting for or accompanying those receiving medical treatments, or work activities separate from those of the facility like making deliveries to/from the facility. Further, it is reasonable to assume that the majority of these individuals will be adults and that the time of exposure of any children will be small when compared to the lifetime of exposure that is considered when determining acceptable risks for stochastic health effects.

Therefore, the NRC is proposing to amend its regulations to provide that, as long as a licensee or applicant establishes appropriate dose management measures (e.g., signage, information briefings and area monitoring to ensure compliance with the proposed higher annual dose limit), a higher public dose limit within the controlled area may be approved on a case-by-case basis. The NRC's case-by-case review would consider such things as the likely cumulative exposure of a member of the public under the proposed new dose limit given the time that the member of the public is expected to be within the controlled area and the effectiveness of the proposed dose management measures.

Second, in § 20.1301(d), the NRC is proposing to remove references to ALARA, to remove the upper limit on the annual dose limit for a member of the public that may be requested (which is currently set at 500 mrem per year), and to specify the information that is required in an application by a licensee or applicant for prior NRC authorization, on a case-by-case basis, for a public dose limit in excess of 100 mrem per year. The regulation at § 20.1301(d) was originally intended to provide a process for facilities existing at the time of the regulatory changes implemented in 1991 that found it difficult to meet the then newly enacted public dose limit of 100 mrem per year (see 56 FR 23360). However, the NRC now proposes to clarify that any licensee or applicant can apply for a higher public dose limit by providing the information required by the regulation, which the NRC will review on a case-by-case basis. Specifically, such an application must: (1) demonstrate the need for and the expected duration of operations in excess of the public dose limit; (2) describe the licensee's program to assess and control dose within the proposed higher limit; and (3) provide a supporting basis for the proposed higher limit, including why it remains protective of the public health and safety. Such a request for a higher public dose limit for the unrestricted area would require a more detailed analysis than a request for a higher public dose limit for the controlled area because of the lack of control that a licensee can exert over the unrestricted area and the presumably larger population that could potentially be subject to the proposed higher doses. Because of the statistical nature of stochastic health effects, the larger the population that receives a given dose, the larger the potential health impact. Therefore, it is likely that the NRC would generally reserve approvals for higher public dose limits that are limited in duration and/or demonstrated to have limited population impacts.

In their applications, in order to demonstrate that the requested higher public dose limit remains protective of the public health and safety, licensees and applicants could apply the critical group or representative person concepts described in ICRP

Publication 101, and earlier ICRP references, to perform prospective dose assessments. Determinate or probabilistic assessments, or a combination of both, could be used to support the request. Habit data and physiological characteristics should be representative of the affected population and not overly conservative in terms of assumptions. Additionally, licensees and applicants may consider the use of dose constraints, additional environmental monitoring, and land use censuses as part of their programs to assess and control dose within the proposed higher dose limits.

In addition to the proposed changes to allow requests for NRC authorization, on a case-by-case basis, for higher public dose limits in the controlled area and in the unrestricted area, the NRC is proposing two other changes to the requirements at § 20.1301: (1) changes to the limits that apply to caregivers of patients who cannot be released, and (2) deletion of the short-term dose rate limit for external sources in the unrestricted area.

First, the NRC is proposing to allow higher doses to members of the public who visit and/or care for medical patients who cannot be released under the provisions of § 35.75. Limits that apply to patient release are contained in 10 CFR part 35. The NRC has long permitted a member of the public to receive up to 500 mrem at the Authorized User's (AU) discretion under § 20.1301(c). Additionally, the NRC has approved several exemptions to this regulation as described in Regulatory Issue Summary (RIS) 2006-18, "Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients." These exemptions allowed a caregiver to receive up to 2 rem, by default, with the flexibility to increase that amount if it was too low for a particular case. Similar to these previously issued exemptions, the NRC proposes to revise § 20.1301(c) to include a 2-rem limit for a caregiver and a 500-mrem limit for a non-caregiver member of the public per administration regimen. These limits are independent of the patient release regulations in 10 CFR 35.75, and doses accrued by caregivers or non-caregiver

members of the public from exposure to a patient prior to release do not contribute to the patient's release evaluation. The guidance in RIS 2006-18 and the exemption process remain available to licensees should they desire to pursue authorization, on a case-by-case basis, to exceed the proposed new 2-rem limit for caregivers.

Amending the regulations to allow caregivers to receive up to 2 rem without a licensee requesting and having approved an exemption increases licensee flexibility, reduces regulatory cost and burden, and enables licensees to provide more timely care to patients while maintaining the public health and safety. The justification for the higher limit to the caregiver (i.e., 2 rem instead of 100 mrem) is that it is beneficial, or possibly essential, to the wellbeing of the patient for caregivers to have access to the patient and may, therefore, be considered an element of the patient's medical treatment. Caregivers are usually members of the patient's family or someone close to the family or the patient. Caregivers receive no financial compensation for the comfort or support that they provide a patient and knowingly consent to being exposed above the public dose limit.

Additionally, the higher dose limit is temporary and would not significantly impact the caregiver's lifetime fatal cancer risk. Similarly, the justification for the higher limit to the non-caregiver (i.e., 500 mrem instead of 100 mrem) is that the higher dose limit is temporary and would not significantly impact the individual's lifetime fatal cancer risk. A non-caregiver being exposed in a situation relevant to § 20.1301(c) is likely also a family member or a friend of the patient, thus their access to the patient provides relief during medical treatment. In ICRP Publication 60—which provided the ICRP's first set of comprehensive recommendations after the recommended public dose limit was changed to its current value—the ICRP stated in paragraph 192 that, "Since the detriment is a function of the accumulation of dose over many years, it would be unduly restrictive to require the controls to be related rigidly to annual dose limits. Some flexibility in the limits is desirable." Accordingly, with this proposed rulemaking the NRC is proposing to

exercise this flexibility as it relates to patient care.

Second, the NRC is proposing to delete the short-term dose rate limit in the unrestricted area of 0.002 rem in any hour in § 20.1301(b) because it serves no safety purpose that is not already achieved by the public dose limit of 100 mrem per year. This is because a member of the public could receive the full 100 mrem annual public dose instantaneously and this fact in and of itself would have minimal safety impact. The actual concern in such a hypothetical case would be that a source that could provide such a high dose rate would most assuredly result in an exceedance of the annual public dose limit in a short period of time and it is that exceedance that would require appropriate corrective actions and not the exceedance of any rate limit in receiving the dose. Licensees can voluntarily include short-term dose rate limits within their radiation protection programs for the purposes of dose management or to facilitate investigations of abnormal conditions; however, these are not necessary in addition to the annual public dose limit for the protection of the public health and safety. Therefore, the NRC is proposing to delete § 20.1301(a)(2) and the provision in § 20.1302(b)(2)(ii) that references 2 mrem in an hour.

License Termination Criteria

The NRC is proposing to revise the license termination criteria in 10 CFR part 20 subpart E to make conforming changes based on the discontinuation of the use of ALARA terminology in the NRC's regulations and guidance. Specifically, the NRC is removing the terms "as low as reasonably achievable" and "ALARA" from subpart E and replacing them, as appropriate. As explained previously in this document, the NRC's regulations and guidance would continue to use justification and optimization analyses to satisfy the original intent of the ALARA principle of, in this instance, reducing residual radioactivity to levels where further reductions would not be justified for both unrestricted and restricted use. The NRC intends for licensees to continue providing a combination of

qualitative and quantitative analyses consistent with the guidance in NUREG-1757, volume 2, appendix N to satisfy the requirement to justify such reductions in residual radioactivity.

Additionally, the NRC is proposing to include a reference to § 20.1406(c) to its radiological criteria for unrestricted use at § 20.1402 to emphasize that the reduction in residual radioactivity may be justified by actions already taken by the licensee to minimize contamination. For example, licensees may be able to take credit for performing dismantlement and remediation activities in a way that minimizes the introduction of contamination to the environment in the analysis to demonstrate that further reductions are not justified. The NRC's proposed reference to this requirement would provide additional flexibility in the justification analysis required to comply with the proposed radiological criteria for unrestricted and restricted use.

With respect to restricted use, under § 20.1403 and § 20.1404, the NRC is proposing to increase clarity for licensees to demonstrate compliance with the proposed requirement that further reductions in residual radioactivity necessary to comply with the provisions of § 20.1402 would not be justified. Currently, licensees must demonstrate that such reductions either would result in net public, or environmental harm or are consistent with ALARA. The NRC is proposing to introduce significantly more clarity by updating the requirement to include an explicit option to provide a cost-benefit analysis.

Finally, the NRC is making the language in 10 CFR part 20 subpart E consistent by using the broader term "traffic accidents" throughout instead of sometimes using the narrower term "deaths from transportation accidents." The term "traffic accidents" encompasses the term "deaths from transportation accidents."

Respiratory Protection

The NRC is proposing to make changes to its respiratory protection regulations to enable more efficient authorizations of respiratory equipment and their use. Currently,

licensees are required to obtain individual authorization from the NRC in order to: (1) use respiratory equipment that has not been authorized by the National Institute for Occupational Safety and Health (NIOSH), and (2) use assigned protection factors (APFs) in excess of those specified in 10 CFR part 20. Through this rulemaking, a licensee would be allowed instead to reference approvals that the NRC has already issued to other licensees to use non-NIOSH certified equipment and/or to exceed the APFs in 10 CFR part 20; provided that the conditions in the safety evaluations used by the NRC to justify such approvals are applicable to that licensee. Effectively, this would mean that the NRC would only have to review and approve the use of new equipment or APFs once, and subsequent licensees could avail themselves of those approvals to the extent that they apply in their cases. This change would facilitate the use of modern equipment while minimizing risk and administrative burden because regulatory experience has shown that these reviews have not significantly differed once a precedent is established. In cases where the conditions of prior approvals would not apply or where licensee use of the equipment would not be within the scope of what the NRC considered in its safety evaluation, the licensee would have to individually apply for authorization as the regulations currently require.

Doses Received by a Member of the Public due to Byproduct Material Administered for Medical Purposes

The NRC is proposing changes to 10 CFR part 35 regarding the release of patients who have been administered byproduct material. The first proposed change would add to 10 CFR 35.2 the definitions of “caregiver” and “administration regimen.” The proposed definition of “caregiver” is an adult who provides the patient with support or comfort for non-commercial gains following administration of byproduct material. The proposed definition of “administration regimen” is the course of administrations of a given radiopharmaceutical or brachytherapy source as intended by the authorized

user. The second proposed change would amend 10 CFR 35.75 to add a provision to allow a consenting caregiver, who has been educated on the risks of radiation exposure, to receive up to 5 rem (i.e., the occupation dose limit of 10 CFR 20.1201) per patient administration regimen. The dose limit to the general public would remain at 0.5 rem; however, the rule would be revised to specify that this limit is per administration regimen instead of per release. The third proposed change would amend 10 CFR 35.2075 to remove the requirement to keep records of dose evaluations for individual releases that meet certain criteria. Instead, the proposed change would require licensees to develop, implement, and maintain a written procedure for ensuring that a member of the public is not likely to exceed the established limits. The licensee would be required to retain this procedure for the duration of the license. Additionally, the proposed change would remove the requirement to document each instance where instructions are given to a breastfeeding patient.

In 2002, the NRC adopted the current dose-based criteria used in 10 CFR 35.75. At that time, the patient release framework was developed to address brachytherapy implants and single administration therapies (e.g., I-131 therapy for conditions of the thyroid). Also at that time, other applications of byproduct material use in medicine did not involve quantities that would warrant concern regarding the release of patients. The medical landscape has evolved substantially since the current 10 CFR 35.75 was put in place. Namely, radiopharmaceuticals are increasingly being administered over a series of administrations as a matter of protocol, instead of all at once. With the proposed changes to 10 CFR 35.75, the NRC intends to adapt its patient release framework to better address the evolving use of byproduct material in medicine. While the limit for dose received by an individual member of the public is 0.5 rem per patient administration regimen, the NRC is proposing to introduce flexibility through the identification of a caregiver, who is eligible to receive up to the occupational dose limit (i.e., 5 rem) per

patient administration regimen. Individuals identified as caregivers (e.g., spouses, parents) are likely to receive the most dose as a result of a given patient release due to high duration or close contact activities, such as co-sleeping. Other members of the public are unlikely to receive a dose on the same order of magnitude as these potential caregivers. This is reflected in DG-8061 (the proposed revision 2 to Regulatory Guide (RG) 8.39) by using an assumed occupancy factor of 0.25 at 1 meter for a general member of the public (also referred to as a bystander) and an assumed occupancy factor of 1 at 1 meter for a caregiver in the tables provided. RG 8.39 contains additional information regarding patient-specific calculations for added flexibility, including lower occupancies for both caregivers and other members of the public.

The NRC is also proposing to change the recordkeeping requirements for patient release outlined in 10 CFR 35.2075 to better align with common practice. Most patients are likely to fall into certain categories that a licensee has previously determined to be compliant with release in accordance with 10 CFR 35.75. It is unnecessarily burdensome for licensees to retain the bases of release for individual patients who are released in such a way. As such, the NRC is proposing to instead require licensees to develop, implement, and maintain a written procedure for releasing patients in accordance with 10 CFR 35.75. The NRC is also proposing to remove the requirement to individually document when a breastfeeding patient has been given instructions following administration of byproduct material. The procedures required by the proposed 10 CFR 35.75 should detail the process for ensuring compliance for all patients who have been administered byproduct material, including situations where licensees provide instructions to patients who are breastfeeding. This change is intended to alleviate the burden associated with prescriptive recordkeeping requirements and to instead focus on the need to maintain a robust patient release program that enables the treatment of patients while protecting members of the public.

For patients who cannot be released under 10 CFR 35.75, the NRC is proposing to amend 10 CFR 20.1301 to incorporate into that rule flexibilities introduced in RIS 2006-18. The proposed changes to 10 CFR 20.1301(c) would permit licensees, without having to apply for an exemption, to allow a caregiver, newly defined in the proposed changes to 10 CFR part 35, to receive up to 2 rem while providing care to a patient who cannot be released under 10 CFR 35.75. Any receipt of dose in excess of 2 rem would still require an application for an exemption and case-by-case prior approval by the NRC.

In 2002, the NRC amended 10 CFR part 20 to allow some visitors of patients who cannot be released under 10 CFR 35.75 to receive up to 500 mrem. At that time, the NRC acknowledged that, because visitors are often family members or close friends of patients, there is a substantial benefit that outweighs the risk of additional exposure. However, as the medical use of byproduct material has changed, it has come to the NRC's attention that a limit of 500 mrem is insufficient and overly cautious for some situations. While RIS 2006-18 does not set a maximum dose for which a licensee may apply for an exemption, 2 rem is the established initial dose limit for the outlined exemption. The NRC has already deemed a limit of 2 rem adequately protective for situations where a caregiver is necessary while a patient is hospitalized, provided that the licensee justifies the use of the exemption. The proposed rule would therefore eliminate the need for licensees to apply for an exemption for caregiver doses up to 2 rem. For caregiver doses in excess of 2 rem, licensees may still refer to RIS 2006-18. Note that caregiver doses received prior to the patient's release do not contribute to the 5 rem allowed by 10 CFR 35.75 following release. Finally, the proposed update to 10 CFR 20.2107 would require licensees to retain a record of the justification for a caregiver's dose for three years following the exposure.

Industrial radiography

The NRC is proposing to remove from 10 CFR part 34 the definition of the term "ALARA" in § 34.3 and the prescriptive list of the radiation safety officer (RSO) responsibilities in § 34.42(c), which includes the term "ALARA." Removing this term is consistent with the other changes being made as part of this rulemaking and removing the RSO responsibilities is consistent with other similar descriptions of requirements for RSOs. Licensees would continue to be able to look to guidance in NUREG-1556, volume 2, for more detailed information regarding the responsibilities of an RSO for industrial radiography.

Uniform Waste Manifest Forms

The NRC is also proposing changes to 10 CFR part 20 appendix G to provide additional clarity and flexibility on how the information requested on the Uniform Waste Manifest forms (NRC Forms 540 and 540A, 541 and 541A, and 542 and 542A) could be provided. The proposed changes would clarify that the Manifest does not need to include these NRC forms themselves as long as the Manifest reflects the information requested on the applicable NRC forms. Other proposed changes would remove language specifying when NRC Form 540 must physically accompany a shipment and would instead reference Department of Transportation (DOT) regulations. This change would ensure that the NRC's regulations are consistent with the DOT's regulations, including potential future changes to the DOT's regulations. The remaining proposed changes would add clarity and correct minor grammatical errors.

Clarifying Changes to Appendix A to 10 CFR Part 40

The NRC is proposing a change to the introduction section of Appendix A to 10 CFR part 40. The purpose of this change would be to clarify that the use of the phrase "as low as is reasonably achievable" in Appendix A has the same meaning as in EPA's generally applicable standards in 40 CFR part 192, which is different than how NRC has traditionally used ALARA. In this context, the use of the phrase "as low as reasonably

achievable" is focused on the technical practicability of corrective actions. The remaining proposed changes to Appendix A are consistent with the proposed changes to 10 CFR part 20 in that they would require licensees to manage dose within the applicable limits and would require that practicable dose reduction measures be taken. The proposed changes would remove any language that implies that further dose reduction is required. In this context, the phrase "as low as reasonably achievable" will remain in Appendix A, Criterion 5B(6) to conform to EPA's generally applicable standards in 40 CFR part 192.

Conforming Changes to 10 CFR Parts 50, 61, 71, and 72

This proposed rule would also include additional conforming changes to align with the removal of references to ALARA. This includes the removal of a reference to ALARA in 10 CFR 50.66 and in 10 CFR 71.78. Additionally, removals of references to ALARA are proposed in 10 CFR part 72, specifically in §§ 72.3, 72.24, 72.44, 72.104, and 72.126. The changes proposed to § 72.44(d)(3) are conforming changes to align with the proposed changes to effluent reporting requirements in 10 CFR 50.34a, which are discussed in the previous section entitled "Effluents."

Finally, the NRC is proposing to revise the public dose limits in 10 CFR part 61 to make conforming changes based on the discontinuation of the use of ALARA terminology in the NRC's regulations and guidance. Specifically, the NRC is proposing to remove the terms "as low as reasonably achievable" and "ALARA" from subpart C, "Performance Objectives."

Conforming Changes to 10 CFR Part 53

The changes proposed in this rulemaking necessitate conforming changes to the recently issued 10 CFR part 53. In general, these changes serve two purposes. First, they acknowledge that licensees may potentially use dosimetry systems that provide results in terms of total effective dose, as opposed to total effective dose equivalent. Second, they provide the additional flexibility that is being included in the proposed

changes to the NRC's overall radiation protection regulatory framework based on the agency's reconsideration of its use of the LNT model and its application of the ALARA principle.

The regulations at § 53.210, § 53.425, and § 53.530 are proposed to be revised to add reference to total effective dose to the units for dose-based criteria. Additionally, footnote 1 to § 53.210 is proposed to be revised to delete "TEDE" as the designation of the type of effective dose is not central to the purpose of the footnote, rather the magnitude of the dose is. The requirements at § 53.850 are proposed to be revised to change "limiting" to "controlling" to be consistent with the intent of effluent monitoring and control measures. Additionally, § 53.850(b)(2) is proposed to be revised to remove reference to the "Annual Radiological Environmental Operating and Radioactive Effluent Release Reports," in lieu of a more generalized requirement for an effluent program to retain records and develop reporting criteria. This change conforms to changes being proposed in this rulemaking for radiological effluent monitoring and control through revisions to § 50.34a, § 50.36a, and Appendix I to 10 CFR part 50. Lastly, § 53.1645(a) is proposed to be revised to add a process that conforms to the framework being proposed in this rulemaking for the monitoring and control of radiological effluents.

Updates to Design Basis Accident Dose-Based Acceptance Criteria

The NRC has historically used dose-based acceptance criteria when evaluating certain aspects of licensee safety assessments associated with applications for new reactors (e.g., § 50.34(a)(1)). Some of these safety assessments end up forming part of the current licensing basis of the facility after the NRC issues its license. Specifically, some of the accidents that are analyzed in these safety assessments are used to set the design basis of plant equipment to ensure public health and safety. These accidents are known as "design basis accidents." Once incorporated into the current licensing basis, the assumptions, methodology, and equipment (including structures, systems, and

components) are controlled as required by licensing-related regulations (e.g., § 50.90, § 50.59). The NRC has established dose-based acceptance criteria that recognize that certain design basis accidents have a higher assumed frequency of occurrence than others. To maintain the balance provided by the risk triplet—whereby changes in likelihood of occurrence of an accident may be offset by changes in consequences in order to control the risk of an event—the NRC has historically assigned a lower dose-based criteria value (i.e., lower consequence) for accidents that are more likely to occur. In NRC guidance documents (e.g., Branch Technical Positions and the Standard Review Plan in NUREG-0800) this approach is evidenced through the use of "well within," or "a small fraction of" terminology in reference to fractions of the dose-based acceptance criteria used to evaluate the consequences of the maximum hypothetical accident described in Footnote 3 of § 50.34.

Historically, the NRC has interpreted the term "well within" to mean 25 percent of the dose resulting from a maximum hypothetical accident (or 6.3 rem) and the term "small fraction of" to mean 10 percent of the dose resulting from a maximum hypothetical accident (or 2.5 rem). This approach is implemented in Table 7 in RG 1.183, Revision 1, "Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors," dated October 2023 (ML23082A305), but the practice can be observed in other guidance, such as Branch Technical Positions and the Standard Review Plan in NUREG-0800.

With this rulemaking, the NRC is proposing to adopt a single, dose-based acceptance criterion of 10 rem TEDE for design basis accidents that currently use criteria derived from fractions of the maximum hypothetical accident criterion of 25 rem TEDE. With this change the NRC will stop using the "well within" and "small fraction of" qualitative designations and their corresponding numerical values and instead use 10 rem TEDE. This new, dose-based acceptance criterion would apply at locations that are

evaluated for radiological consequences (i.e., exclusion area boundary and low population zone). Regulatory experience indicates that significant applicant, licensee, and NRC staff resources are expended in evaluating the results of these analyses, to include assumptions and plant configurations that support conclusions that the dose criteria are met. Additionally, licensees may encounter situations where equipment that has been determined as being necessary to satisfy the existing dose-based criteria becomes inoperable, sometimes necessitating emergent licensing actions to continue plant operations. These outcomes are not consistent with the safety significance of conservatively calculated doses on the order of 2.5 rem and 6.3 rem resulting from analyses of postulated events that have a very low probability of occurrence. This regulatory experience, combined with the knowledge that deterministic health effects do not occur below 10 rem and that there is a reasonably likelihood that stochastic health effects below 10 rem have been overestimated, supports this proposal.

To implement this proposal, the NRC would revise Table 7 in RG 1.183. This guidance would be issued subsequent to this rulemaking as part of the NRC's planned two-phased approach to issuing guidance associated with this rulemaking, see Section VI, "Availability of Guidance," for more information. Additional guidance documents identified by the NRC will be updated on a timeline separate from the rulemaking schedule.

V. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on the proposed rule. The NRC is particularly interested in comments and supporting rationale from the public on the following:

Question 1: The NRC is seeking input from the public on the proposed rule. The NRC is

interested in comments and supporting rationale from the public regarding the implementation of proposed 10 CFR 20.1301(b), which would allow licensees and applicants to request higher dose limits for members of the public who access the controlled area, as defined in 10 CFR part 20. As explained in the proposed rule, the NRC would review these requests on a case-by-case basis and would provide individual approvals if the NRC determined that there was reasonable assurance of adequate protection of public health and safety.

A) As it pertains to the proposed process of case-by-case reviews of requests for higher annual dose limits to members of the public who access the controlled area,

   i. Would a performance-based method be an acceptable means of justifying such requests? For example, a performance-based method could rely on an integrated analysis of relevant factors (e.g., radiological hazards, occupancy, and access conditions) to demonstrate that members of the public are unlikely to receive doses exceeding the annual public dose limit in 10 CFR 20.1301(a).

   ii. Under an applicant driven, case-by-case analysis, how should NRC evaluate applicant requested justifications?

   iii. What factors should the NRC consider in evaluating these requests (e.g., health risks, duration of entry, proximity to population centers, demographics, accessibility to the controlled area, national security, energy reliability, undue hardship, cost considerations), and how should these factors be prioritized?

   iv. Similar to other protective measures (i.e., such as postings for high voltages at electrical substations), what measures would be appropriate to provide notice and protection to members of the public in such cases including any special subgroups such as transient workers, minors, pregnant or breast feeding women, etc.?

B) Alternatively, or in addition to the previously discussed case-by-case review and approval process, should the NRC increase the annual public dose limit of 10 CFR 20.1301(a) within the controlled area?

   i. What dose management measures would be appropriate in such cases?

   ii. Additionally, would it be sufficient for these dose management actions to be implemented through a licensee's radiation protection program, which is required by 10 CFR 20.1101, and verified through NRC inspection?

   iii. Finally, under such an option, what should the annual dose limit be for members of the public who access the controlled area under these circumstances?

Question 2: What are the expected benefits (e.g., simplified design/construction, costs, operational efficiency) and drawbacks (e.g., additional dose management and controls, periodic monitoring of population, stronger access controls) of allowing higher annual dose limits to members of the public who access the controlled area and, in limited circumstances, outside the site boundary? What specific use cases are expected to leverage these flexibilities and what operational or design benefits are anticipated for these use cases if the flexibilities are adopted? Please provide quantitative information and description of use cases to the extent possible; however, qualitative assessments would be useful, as well.

Question 3: The NRC requests comments and supporting rationale on proposed 10 CFR 20.1301(d), which would allow licensees and applicants to request, on a case-by-case basis, higher public dose limits than those in 10 CFR 20.1301(a) when there is reasonable assurance of adequate protection of public health and safety.

A) What factors should the NRC consider when evaluating these requests (e.g.,

dose control measures, health risks, proximity to population centers, demographics, land ownership, national security, energy reliability, cost considerations), and how should these factors be prioritized?

B) Are there scientific considerations the NRC should take into account when reviewing requests for increased dose limits on a case-by-case basis? Quantitative or qualitative information is useful.

C) Based on practical use cases and consistent with the NRC's intent for the flexibility in 10 CFR 20.1301(d), as described in the preamble, the NRC seeks input on the advantages and disadvantages of public dose limit flexibility allowed through 10 CFR 20.1301(d) and potential qualitative or quantitative limits on flexibility in guidance or regulatory text that the NRC should consider. Are there any practical use cases that would be challenged by a limitation on the flexibility allowed in 10 CFR 20.1301(d)?

Question 4: The NRC proposes to introduce the concept of the caregiver in the patient visit and release-related regulations in parts 20 and 35, respectively. This will enable people who are essential to the care and well-being of patients receiving radiopharmaceutical treatments to willingly receive higher doses than members of the general public, if needed. As part of this regulatory change, while the NRC is maintaining the dose limit to members of the public from patient release at 500 mrem, the NRC proposes to revise the basis for calculating doses to members of the public from per-administration to per-regimen. What are the advantages and disadvantages of using a per-regimen basis for patient release determinations? Would this approach create any barriers to treatment access? Alternatively, should the NRC retain a per-administration basis for members of the public but apply a per-regimen basis for caregivers? Please provide quantitative information to the extent possible; however, qualitative assessments

would be useful, as well.

Question 5: The NRC proposes to increase its radionuclide emissions standards from the current regulatory constraint in 10 CFR 20.1101(d) of 10 mrem per year to 25 mrem per year; this change would also be extended to the criteria in 10 CFR part 50, Appendix I. If a licensee releases effluents greater than or equal to the 25 mrem per year constraint, that licensee would be required to submit relevant reports to the NRC on an annual basis until levels are returned to below the 25 mrem per year constraint. Additionally, such a licensee would be required to evaluate and consider implementing cost-justified corrective actions to restore effluent levels to below the 25 mrem per year constraint. The NRC is seeking input from the public on the following related to the proposed changes to effluent constraints and reporting requirements:
Are there alternative approaches the NRC should consider, such as increasing the constraint while retaining existing reporting practices? What are the potential advantages or disadvantages of these alternative approaches?

Question 6: If the public dose limit in 10 CFR 20.1301(a) were increased, what level would be appropriate and why? What would be the advantages and disadvantages of such a change? Please provide the technical basis for your response, including quantitative or qualitative information supporting that basis.

VI. Availability of Guidance

The NRC is issuing draft guidance for implementation of the proposed requirements in this rulemaking in two phases. Three guidance documents will be issued for public comment at the same time as this notice. Additional guidance documents will be issued for public comment following the publication of the proposed rule. The draft

guidance documents issued for comment concurrently with this proposed rule are available in ADAMS as described in the “Availability of Documents” section. When finalized, the documents will provide stakeholders with guidance for implementing the final requirements contemplated by this proposed rule. You may submit comments on the draft regulatory guidance by the methods outlined in the ADDRESSES section of this document. Additional guidance documents identified by the NRC will be updated on a timeline separate from the rulemaking schedule.

VII. National Environmental Policy Act

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission’s regulations in subpart A of 10 CFR part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The bases for this determination are documented in the draft environmental assessment, listed under the “Availability of Documents” section and incorporated by reference in this proposed rule. As explained in the draft environmental assessment, the implementation of the proposed rule described in this Federal Register Notice would not have a significant environmental impact. Public comments on the draft environmental assessment may be submitted to the NRC as indicated under the ADDRESSES section of this document.

VIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. Therefore, in accordance with section

605(b), the NRC is not preparing a regulatory flexibility certification analysis. The rule will in fact apply to the many small entities that are among the NRC licensees, applicants, and petitioners for rulemaking, but it will impose no new burden on those small entities. To the contrary, as noted in the regulatory analysis section of this notice, the agency's expectation is that the rule will reduce burden.

IX. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as indicated in the "Availability of Documents" section of this document. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the ADDRESSES section of this document.

X. Backfitting and Issue Finality

The NRC has determined that the backfitting provisions in 10 CFR parts 50, 53, 70, 72, and 76 and the issue finality provisions in 10 CFR part 52 are not implicated by this proposed rule. While the proposed changes would predominantly affect regulations in 10 CFR part 20 and would thus impact all categories of NRC licensees, including those entities within the scope of backfitting or issue finality provisions, none of the proposed revisions in this rulemaking would constitute backfitting or affect issue finality. Each proposed amendment in this rulemaking is either in the form of a voluntary relaxation or the addition of an alternative option for compliance with applicable NRC regulations. For example, while the NRC is proposing to discontinue the use of ALARA terminology in its regulations and guidance and introduce a graded approach to dose

management in its place, a licensee would not be required to modify or add to its operating procedures because compliance with regulations implementing the current ALARA terminology would also be sufficient to satisfy the revised regulations implementing the graded approach to dose management. Therefore, because the NRC would not be imposing new or revised requirements on an applicable entity, the NRC has determined that the proposed revisions would not constitute backfitting as defined in 10 CFR parts 50, 53, 70, 72, and 76 or affect the issue finality of an existing approval issued under 10 CFR part 52.

XI. Cumulative Effects of Regulation

The NRC seeks to minimize potential negative consequences resulting from the cumulative effects of regulation (CER). The NRC believes that the de-regulatory impacts of this rulemaking activity are unlikely to cause implementation challenges for stakeholders. In addition, during the pendency of this rulemaking, the NRC is deprioritizing issuance of regulatory actions that might influence the implementation date for the new rule requirements (e.g., orders, generic communications, license amendment requests, and inspection findings of a generic nature).

To fully understand any potential CER implications that could result from this rulemaking, the NRC is asking the following questions. Response to these questions is voluntary and any input will be considered during development of the final rule.

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

XII. 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 document 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 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XIII. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections. The proposed changes to 10 CFR parts 19, 40, 61, and 71 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995.

Type of submission, new or revision: New

The title of the information collection: Reforming and Modernizing the NRC's Radiation Protection Framework

The form number if applicable: None

How often the collection is required or requested: Once, on occasion, annually. Under

the proposed rule, information collections would be generally required on occasion, such as when certain applications are submitted to the NRC for review, and when exposures occur that require a report. Certain reports, such as ones specifying the quantity of principal radionuclides released, would be required at least once per year. Recordkeeping requirements would mandate that some records be retained for three to five years, while others are to be maintained for the duration of a license, depending on the specific regulation. Forms and other reports would be submitted at the time of specific events.

Who will be required or asked to respond: NRC licensees under parts 20, 34, 35, 50, 53, or 72.

An estimate of the number of annual responses:

10 CFR part 20: -45.0 (-162.0 reporting responses + 99.0 recordkeepers + 18.0 third-party disclosures)

10 CFR part 34: -594.0 (0.0 reporting responses + -594.0 recordkeepers + 0.0 third-party disclosures)

10 CFR part 35: 7,650.0 (0.0 reporting responses + 3,825.0 recordkeepers + 3,825.0 third-party disclosures)

10 CFR part 50: 300.0 (150.0 reporting responses + 150.0 recordkeepers + 0.0 third-party disclosures)

10 CFR part 53: 0.0 (0.0 reporting responses + 0.0 recordkeepers + 0.0 third-party disclosures)

10 CFR part 72: 170.0 (85.0 reporting responses + 85.0 recordkeepers + 0.0 third-party disclosures)

The estimated number of annual respondents:

10 CFR part 20: 99 Respondents

10 CFR part 34: 0 Respondents

10 CFR part 35: 3,825 Respondents

10 CFR part 50: 150 Respondents

10 CFR part 53: 0 Respondents

10 CFR part 72: 85 Respondents

An estimate of the total number of hours needed annually to comply with the information collection requirement or request:

10 CFR part 20: -2,070.0

10 CFR part 34: -33,264.0

10 CFR part 35: -1,963.5

10 CFR part 50: 0.0

10 CFR part 53: 0.0

10 CFR part 72: 0.0

Abstract:

The NRC is proposing to amend its regulations that govern its standards for protection against radiation. The revisions reflect the agency's reconsideration of its use of the LNT model for assessing health effects from radiation exposure and its application of the ALARA principle that is predicated on the LNT model. The proposed rule would reflect the NRC's experience and other developments in the field of radiation protection since the NRC's last major revisions to these standards in 1991.

The proposed rule covers diverse topics, which result in recordkeeping and reporting requirements related to instruction to workers, radiation protection requirements, industrial radiography, medical use of byproduct material, source material licensing, and storage and transportation of radioactive material.

In addition to the new information collections in the proposed regulations, this proposed rule would result in amended requirements for NRC Forms 540/540A, 541/541A, and 542/542A. These forms are used on a nationwide basis to reflect the minimum safety-related information for a low-level radioactive waste shipment as required by Federal and State reporting requirements for the safe transportation and disposal of low-level radioactive waste. The rulemaking would not make any changes to the forms themselves. The rulemaking would make the use of the forms optional as long as respondents provide the same information as required in the forms using a different format.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your answer.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your answer.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package and proposed rule are available in the

"Availability of Documents" section of this document or may be viewed free of charge by contacting the NRC's Public Document Room reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. You may obtain information and comment submissions related to the OMB clearance package by searching on https://www.regulations.gov under Docket ID NRC-2025-1140.

You may submit comments on any aspect of this proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following method:

Federal rulemaking website: Go to https://www.regulations.gov and search for Docket ID NRC-2025-1140.

Submit comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Coordination with NRC Agreement States

On February 11, 2026, the NRC held a government-to-government meeting with the Agreement States regarding this rulemaking. On February 12, 2026, the rule was shared with the Standing Committee for Compatibility.

XIV. Compatibility of Agreement State Regulations

On the basis of the "Agreement State Program Policy Statement" approved by

the Commission on October 2, 2017, and published in the Federal Register (82 FR 48535, October 18, 2017), NRC program elements can be placed into six categories (A, B, C, D, NRC, or health and safety (H&S)) to form the basis for evaluating and classifying the program elements. Under the Agreement State Policy Statement, a program element means any component or function of a radiation control regulatory program, including regulations and other legally binding requirements imposed on regulated persons, which contributes to implementation of that program.

Compatibility Category A are those program elements that include basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. Compatibility Category A program elements adopted by an Agreement State should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B pertains to a limited number of program elements that cross jurisdictional boundaries and should be addressed to ensure uniformity of regulation on a nationwide basis. For Compatibility Category B, the Agreement State program element shall be essentially identical to that of NRC.

Compatibility Category C are those program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State program shall embody the essential objectives of the Category C program elements. Under Category C, Agreement State program elements may be more restrictive than NRC program elements; however, they should not be so restrictive as to prohibit a practice authorized by the Atomic Energy Act of 1954 (AEA), as amended, and in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

Compatibility Category D are those program elements that do not meet any of

the criteria of Category A, B, or C, above, and are not required to be adopted by Agreement States for purposes of compatibility. An Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction that are not addressed by the NRC or that are not required for compatibility (i.e., Compatibility Category D). However, such program elements of an Agreement State relating to agreement material shall (1) not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis; (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not preclude the ability of the NRC to evaluate the effectiveness of Agreement State programs for agreement material with respect to protection of public health and safety.

Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the AEA, or provisions of 10 CFR. The NRC maintains regulatory authority over these program elements and the Agreement States must not adopt these NRC program elements. However, an Agreement State may inform its licensees of these NRC requirements through a mechanism under the State's administrative procedure laws, as long as the State adopts these provisions solely for the purposes of notification, and does not exercise any regulatory authority as a result.

Category H&S program elements embody the basic health and safety aspects of the NRC's program elements. Although H&S program elements are not required for purposes of compatibility, they do have particular health and safety significance. The Agreement State must adopt the essential objectives of such program elements to maintain an adequate program.

The proposed rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC

requirements.

The NRC is proposing to assign Category A to following new definitions in 10 CFR Part 20: Committed effective dose", "Committed equivalent dose", "Dosimetry method (or system)", "Effective dose", "Equivalent dose", "Graded approach to dose management", "Planned occupational dose limit extension", "Radiation weighting factor", and "Total Effective Dose." These definitions are necessary to understand radiation protection concepts.

Next, the NRC is proposing to change the compatibility category of 10 CFR 20.1101(b) from Category H&S to Category A. The regulatory history of the rationale for the H&S designation is scant as 10 CFR 20.1101(b), originally issued as 10 CFR 20.1, did not address Agreement State compatibility and adequacy categories because it predated the Agreement State Policy Statement. As the NRC clarified Agreement State categories with the issuance and subsequent updates to the Agreement State Policy Statement, 10 CFR 20.1101(b) was assigned the H&S Category. 10 CFR 20.1101(b), at its heart, ensures that licensees operate their radiation protection program in a manner that ensures compliance with dose limits. The Agreement State Policy Statement provides that Category A, "includes basic radiation protection standards that encompass dose limits, concentration, and release limits related to radiation protection in [10 CFR part 20], that are generally applicable." As such, the NRC is proposing to change the compatibility category of 10 CFR 20.1101(b) because it relates closely to radiation protection standards. Additionally, the proposed graded approach to dose management in revised 10 CFR 20.1101(b) is a critical piece of the overall regulatory framework that ensures that the dose limits in 10 CFR part 20 are not exceeded.

With this proposed change in compatibility category, Agreement States would be required to revise their equivalent 10 CFR 20.1101(b) regulation to be essentially identical to the NRC's and remove the ALARA requirement. Given this proposed

required revision to the ALARA requirement, Agreement States would also remove ALARA references from their equivalent regulations to avoid conflicts, duplications, gaps, and to ensure an orderly pattern in the regulation of agreement material on a nationwide basis. However, the NRC is not proposing to change the compatibility or adequacy category of every regulation where references to ALARA should be removed. To assist states, the following is a non-exhaustive list of those regulations with references to ALARA where Agreement States would be required to either remove their equivalent regulation entirely (e.g., the definition of ALARA), or remove the reference to ALARA in a regulation that is otherwise Category H&S, C, or D (i.e., those regulations not already required to be essentially identical with the NRC):

1. Remove 20.1003, ALARA definition (previously Category A; this proposed rule would remove this definition entirely)
2. 20.1402 (previously Category C; note that the NRC is proposing to revise this designation for certain licensees)
3. 20.1403(a) (previously Category C; note that the NRC is proposing to revise this designation for certain licensees)
4. 20.1403(e) (previously Category C; note that the NRC is proposing to revise this designation for certain licensees)
5. 20.1404(a)(3) (previously Category C; note that the NRC is proposing to revise this designation for certain licensees) 20.1601(f) (Category H&S)
6. 20.1702 (Category H&S)
7. 20.1704(a) (Category D)
8. 20.2002 (Category D)
9. 20.2105 (Category D)
10. 20.2203(a)(2)(vi) (Category C)
11. 20.2203(b)(iv) (Category C)

12. Remove 34.3, ALARA definition (previously Category A; this proposed rule would remove this definition entirely)
13. Remove 34.42(c) (previously Category D; this proposed rule would remove this definition entirely)
14. 35.75(b) (Category C)

The NRC is also proposing revisions to remove references to ALARA in 10 CFR 71.87(i), which is compatibility Category B. The NRC is not proposing to change the compatibility category for that regulation. Thus, Agreement States would be required to ensure that their equivalent regulations be essentially identical to the NRC's proposed revisions in 10 CFR 71.87(i) and, therefore, remove references to ALARA in said regulation.

The NRC recognizes that the removal of ALARA references is not as straightforward in 10 CFR part 20 subpart E (10 CFR 20.1402, 20.1403(a), 20.1403(e), 20.1404(a)(3), 20.1601(f)). The compatibility categories of these sections remain Category C except for certain licensees as noted in the Table below. The essential objective of 10 CFR part 20 subpart E still remains to provide a licensee with a pathway to terminate its license for unrestricted or restricted use. This rulemaking clarifies that the essential objective also includes that residual radioactivity be managed within the applicable limit and not be required to be managed significantly below that limit. Thus, while Agreement States would be required to remove references to ALARA in 10 CFR part 20 subpart E, and the other sections referenced above, to prevent a disorderly pattern of regulation nationwide, Agreement States have flexibility in revising their regulations to be consistent with the clarified essential objectives of 10 CFR part 20 subpart E. For ease and consistency, the NRC encourages Agreement States to follow NRC's model in revising 10 CFR part 20 subpart E.

The NRC is also proposing changing the compatibility category for 10 CFR 20.1101(d) from Category C to Category A. 10 CFR 20.1101(d) provides standards for air emissions of radioactive material to the environment, other than Radon-222, for licensees other than those subject to 10 CFR 50.34a (i.e., power reactors). In 1996, the NRC issued this requirement to provide assurance to the U.S. Environmental Protection Agency (EPA) that future emissions from NRC licensees (other than power reactors, which were addressed separately) would not exceed dose levels that the EPA had determined would provide an ample margin of safety under Section 112(d)(9) of the Clean Air Act (CAA) (42 U.S.C. 7412(d)(9); 61 FR 65120, December 10, 1996). The 1996 rulemaking thus provided EPA a basis upon which to rescind its own CAA regulations for NRC licensed facilities and Agreement State licensees, thereby relieving these licensees from unnecessary dual regulation.

Notably, in the 1996 rulemaking, the *Federal Register* notice stated that the new 10 CFR 20.1101(d) codified "numerical values for NRC's application of ALARA guidelines for radioactive air emissions from its licensees, other than power reactors." However, with this proposed rule, the NRC is replacing ALARA with a graded approach to dose management in revised 10 CFR 20.1101(b), which the NRC is proposing to assign a compatibility category A. This graded dose management approach consists of regulatory requirements and guidance that ensure that the applicable dose limit is not exceeded. In the proposed rule, the revised 20.1101(d) emissions standards would no longer be implemented by numerical criteria for the application of ALARA guidelines, but instead the emissions standards would be an integral part of the proposed graded approach to dose management in 10 CFR 20.1101(b).

While the CAA does not preclude a state from adopting more restrictive emissions standards for radionuclides, Agreement State programs must be adequate and compatible with the NRC's program under the AEA. Per the Agreement State Policy

Statement, compatibility category A includes those requirements such as “basic radiation protection standards that encompass dose limits, concentration, and release limits related to radiation protection [10 CFR part 20].” Given that the emissions standards in proposed 10 CFR 20.1101(d) serve an integral purpose in ensuring that the dose limits referred to in the revised 20.1101(b) are not exceeded and that the NRC is proposing to designate 10 CFR 20.1101(b) as Category A, 10 CFR 20.1101(d) would also be most appropriately categorized as Category A. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Part 50.34a and 10 CFR 53.260, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

As indicated above, the NRC is proposing to change the compatibility category of the license termination criteria in 10 CFR part 20 subpart E (10 CFR 20.1402, 20.1403(a), 20.1403(e), 20.1404(a)(3), 20.1601(f)) only for certain licensees. Specifically, the NRC is proposing to change the compatibility category of these regulations from Category C to Category B for licensees recovering source material from any mineral resources (includes rare earths and other critical minerals as defined in 90 FR 41591) that are processed primarily for purposes other than obtaining the source material content. Similarly, the NRC is proposing to change the compatibility category for the license termination criteria for the domestic milling of uranium in 10 CFR part 40, Appendix A for Criterion 5 and Criterion 6 from Category C to Category B. Under the Agreement State Policy Statement, Category B “pertains to a limited number of program elements that cross jurisdictional boundaries and that should be addressed to ensure uniformity of regulation on a nationwide basis.” In Management Directive 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs,” the NRC

defines “cross jurisdictional” with respect to Category B as “a practice or licensed activity that necessitates identical requirements to ensure an orderly regulatory pattern for the use and regulation of agreement material between all Agreement States and NRC jurisdictions.”

On January 29, 2025, the President issued E.O. 14156, “Declaring a National Energy Emergency.” That E.O. declares a national energy emergency and instructs heads of agencies to “identify and exercise lawful emergency and other authorities available to facilitate the identification, leasing, siting, production, transportation, refining, and generation of domestic energy resources.” On that same day, the President also issued E.O 14154, “Unleashing American Energy.” That E.O sets forth several United States policies, including “to protect the United States's economic and national security and military preparedness by ensuring that an abundant supply of reliable energy is readily accessible in every State and territory of the Nation.” Subsequently, on May 23, 2025, the President issued E.O. 14299, “Deploying Advanced Nuclear Reactor Technologies for National Security,” which discusses the national security aspects of the need for additional nuclear energy nationwide.

The domestic extraction of some critical minerals, which are established by the U.S. Geological Survey in coordination with responsible agencies and departments, in part to protect national security, may involve the recovery of source material and require licensing by the NRC or an Agreement State. E.O. 14154 speaks directly to the importance of critical minerals in establishing a United States policy “to establish our position as the leading producer and processor of non-fuel minerals, including rare earth minerals, which will create jobs and prosperity at home, strengthen supply chains for the United States and its allies, and reduce the global influence of malign and adversarial states.”

Consistent with the direction of the previously discussed E.O.s as well as the National Materials and Minerals Policy, Research and Development Act of 1980, which ensures the stable supply of materials necessary to maintain national security, this activity necessitates identical requirements to ensure an orderly regulatory pattern for the use and regulation of material between all Agreement States and NRC jurisdictions. The proposed change in compatibility category for these licensees will ensure uniformity for license termination nationwide since the domestic extraction of critical minerals is important for national security.

Similarly, the NRC is proposing to change the compatibility category of 10 CFR part 40, Appendix A for Criterion 5 and Criterion 6 from Category C to Category B. These criteria in 10 CFR part 40, Appendix A contain the groundwater and stabilization and control of material requirements that must be achieved prior to license termination of uranium mills. Criterion 5 establishes applicable groundwater protection standards during operations and prior to the end of closure. Criterion 6 establishes additional requirements for the stabilization and control of material prior to the end of closure. The domestic milling of uranium is an essential part of the nuclear fuel cycle and, therefore, important to national security, consistent with the direction of the previously discussed E.O.s. As uranium milling occurs in multiple jurisdictions, it is important for a consistent approach and understanding of license termination criteria nationwide. Further, a consistent approach is essential to the overall regulatory framework for domestic uranium milling and, therefore, important to the development and growth of domestic uranium milling and to national security, consistent with the direction of the previously discussed E.O.s. Accordingly, the NRC is proposing changing Criterion 5 and Criterion 6 in 10 CFR part 40, Appendix A to Category B as the activity necessitates identical requirements to ensure an orderly regulatory pattern for the use and regulation of material between all Agreement States and NRC jurisdictions.

Importantly, the NRC is not proposing that the license termination criteria for this subset of licensees are matters relating to common defense and security such that they would be exclusively regulated by the NRC. Rather, the national security considerations and Administration's priorities expressed in the above E.O.s underpin the NRC's proposal to designate these activities as Category B, for the identified licensees, as a practice or licensed activity that necessitates identical requirements to ensure an orderly regulatory pattern for the use and regulation of agreement material between all Agreement States and NRC jurisdictions. The NRC recognizes the challenges Agreement States may have in implementing different compatibility categories based on the type of licensed activity and will work with the States on implementation.

For newly proposed 10 CFR 20.1010 and the associated 10 CFR part 20, Appendix H, the NRC is proposing to assign Compatibility Category B. The proposed new regulation, § 20.1010, would reference a listing of generically approved alternative dosimetry methods in a proposed new Appendix H to 10 CFR part 20, and it would also provide the criteria for the NRC’s approval of a method that is not listed in Appendix H. The NRC is proposing to assign these regulations Category B because the use of dosimetry methods is cross-jurisdictional and the uniformity of approved alternatives is necessary to ensure an orderly regulatory pattern for the use and regulation of material between all Agreement States and NRC jurisdictions.

Next, the NRC is proposing to change the compatibility category of 10 CFR 20.1301(d) from Category C to Category A. Currently, 10 CFR 20.1301(d) allows a licensee or applicant to apply for prior NRC authorization to operate in excess of the public dose limit (i.e., 100 mrem) for an individual member of the public, up to 500 mrem, and specifies the information the entity should provide in this application. The proposed revision to 10 CFR 20.1301(d) would remove the 500 mrem upper limit. This change does not affect the ability for Agreement States to approve an optional upper public dose

limit consistent with past practices. With the removal of that upper limit and the regulation tied to the public dose limit of 100 mrem, the NRC proposes designating the regulation Compatibility Category A, consistent with the designation for the public dose limit.

For the newly proposed 10 CFR 20.1205, which concerns a new process for allowing workers to receive occupational doses in excess of applicable annual limits, the NRC is proposing to assign Compatibility Category A. As explained above, this optional process in the newly proposed 10 CFR 20.1205 would allow licensees to periodically exceed annual occupational dose limits for workers, provided that an adequate decision-making process is applied to support its use and that the overall dose is limited within specified multi-year average values. The proposed approach would allow for dose averaging across several years to demonstrate compliance with occupational dose limits. Similar to 10 CFR 20.1301(d) for the public dose limit, 10 CFR 20.1205 allows licensees flexibility with respect to the occupational dose limit. Thus, the NRC proposes designating 10 CFR 20.1205 as Category A, consistent with the designation for the occupational dose limit itself and the similar proposed designation for 10 CFR 20.1301(d) for the public dose limit flexibility. Moreover, in order to protect radiation workers' ability to work in different jurisdictions within the same calendar year when utilizing this provision, it is necessary for all jurisdictions to have the same flexibility built into their regulations.

With respect to 10 CFR part 35, the NRC is proposing to assign compatibility Category B to the new definitions for "Caregiver" and "Administration regimen" as well as the revised 10 CFR 35.75(b) regarding the dose limits for patient release, which means that these requirements have cross-jurisdictional boundaries implications. Agreement States' requirements should be essentially identical to those of the NRC so that there

are consistent standards for patient release requirements between the NRC and the Agreement States.

Since the 2002 adoption of the current dose-based criteria in 10 CFR 35.75, the treatment and release of patients with byproduct materials have undergone a number of significant changes with regard to the doses and administrative regimens of therapeutic radioisotopes used, treatment modalities, and the treatment and release of patient at regional treatment centers that require patients to travel in multiple jurisdictions. These changes require consistent standards to ensure equivalent levels of protection. For example, an increasing number of therapeutic radiopharmaceuticals are being delivered over the course of multiple administrations. Safe implementation of the proposed revision to 10 CFR 35.75(b) relies on consistent application of release considerations over the course of the entire administration regimen, which could be delivered in multiple jurisdictions.

The compatibility (A, B, C, D, and NRC) and adequacy (H&S) categories are designated in the following tables:

Adequacy and Compatibility Table for 10 CFR Part 19

Section	Change	Subject	Compatibility	
			Existing	New
19.12	Amend	Instruction to workers.	C	C
19.13	Amend	Notifications and reports to individuals.	C	C

Adequacy and Compatibility Table for 10 CFR Part 20

Section	Change	Subject	Compatibility	
			Existing	New
20.1003	Amend	Definition – Airborne radioactivity area	A	A
20.1003	Delete	Definition – ALARA	A	
20.1003	Amend	Definition – Annual limit on intake	A	A
20.1003	Amend	Definition – Committed Dose Equivalent	A	A
20.1003	New	Definition – Committed equivalent dose	-	A
20.1003	Amend	Definition – Committed	A	A

		effective dose equivalent		
20.1003	New	Definition – Committed effective dose.	-	A
20.1003	Amend	Definition – Derived air concentration	A	A
20.1003	Amend	Definition – Dose or radiation dose	D	D
20.1003	Amend	Definition – Dose equivalent	A	A
20.1003	New	Definition – Dosimetry method (or system)	-	A
20.1003	New	Definition – Effective dose	-	A
20.1003	Amend	Definition – Effective dose equivalent	A	A
20.1003	New	Definition – Equivalent Dose	-	A
20.1003	New	Definition – Graded approach to dose management	-	A
20.1003	Amend	Definition – License	D	D
20.1003	Amend	Definition – Nonstochastic effect	A	A
20.1003	Amend	Definition – Planned special exposure	D	D
20.1003	New	Definition – Planned occupational dose limit extension	-	A
20.1003	New	Definition – Radiation weighting factor	-	A
20.1003	Amend	Definition – Stochastic effects	A	A
20.1003	New	Definition – Total effective dose	-	A
20.1003	Amend	Definition – Weighting factor	A	A
20.1004	Amend	Units of radiation dose	A	A
20.1010	New	Dosimetry methods.	-	B
20.1101(a) and (c)	Amend	Radiation protection programs.	H&S	H&S
20.1101(b)	Amend	Radiation protection programs	H&S	A
20.1101(d)	Amend	Radiation protection programs	C	A, except portions of these provisions are designated as NRC (Those portions of the

				provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50.34a and 53.260 are designated as a Compatibility Category NRC)
20.1201	Amend	Occupational dose limits for adults.	A	A
20.1202	Amend	Compliance with requirements for summation of external and internal doses.	A	A
20.1204	Amend	Determination of internal exposure.	A	A
20.1205	New	Planned occupational dose limit extension	-	A
20.1206	Amend	Planned special exposures.	D	D
20.1301(a), (b), (c)	Amend	Dose limits for individual members of the public.	A	A
20.1301(d)	Amend	Dose limits for individual members of the public.	C	A
20.1302(b)	Amend	Compliance with dose limits for individual members of the public.	H&S	H&S
20.1302(c)	Amend	Compliance with dose limits for individual members of the public.	D	D
20.1402	Amend	Radiological criteria for unrestricted use.	C	B – for source material recovered from any mineral resources processed primarily for purposes other than obtaining the source material content C – for all other

				Agreement State licensed activities*
20.1403	Amend	Criteria for license termination under restricted conditions.	C	B – for source material recovered from any mineral resources processed primarily for purposes other than obtaining the source material content C – for all other Agreement State licensed activities*
20.1404	Amend	Alternate criteria for license termination.	C	B – for source material recovered from any mineral resources processed primarily for purposes other than obtaining the source material content C – for all other Agreement State licensed activities*
20.1405	Amend	Public notification and public participation.	C	C
20.1502	Amend	Conditions requiring individual monitoring of external and internal occupational dose.	H&S	H&S
20.1601(f)	Amend	Control of access to high radiation areas.	H&S	H&S
20.1702	Amend	Use of other controls.	H&S	H&S

20.1703	Amend	Use of individual respiratory protection equipment.	H&S	H&S
20.1704	Amend	Further restrictions on the use of respiratory protection equipment.	D	D
20.1705	Amend	Application for use of higher assigned protection factors.	B	B
20.1905(b)	Amend	Exceptions to labeling requirements	A	A
20.2002	Amend	Method for obtaining approval of proposed disposal procedures.	D	D
20.2003 (a)(2)&(a)(3)	Amend	Disposal by release into sanitary sewerage.	A	A
20.2004	Amend	Treatment or disposal by incineration.	D	D
20.2101	Amend	General provisions.	C	C
20.2104	Amend	Determination of prior occupational dose.	D or H&S (for States who adopt planned special exposure)	D or H&S (for States who adopt planned special exposure
20.2105	Amend	Records of planned special exposures.	D	D
20.2106(a)	Amend	Records of individual monitoring results.	C	C
20.2107	Amend	Records of dose to individual members of the public.	D	D
20.2202(e)	Amend	Notification of incidents.	D	D
20.2203(a), (b)	Amend	Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.	C	C
Appendix G	Amend	Requirements for Low-level radioactive waste intended for disposal at land disposal facilities and manifests.	B	B
App. G I	Amend	Manifest.	B	B
App. G I	New	Definition – Carrier.	-	B
App. G I	Delete	Definition – Computer readable medium.	B	-

App. G I	Amend	Definition – EPA identification number.	B	B
App. G I	Amend	Definition – High integrity container.	B	B
App. G I	Amend	Definition – NRC Forms 540, 540A, 541, 541A, 542, and 542A.	B	B
App. G I	Amend	Definition – Shipping paper.	B	B
App. G I	Amend	Definition – Uniform Low-Level Radioactive Waste Manifest.	B	B
App. G III.A	Amend	Control and Tracking.	B	B
App. G III.B	Amend	Control and Tracking.	B	B
App. G III.C	Amend	Control and Tracking.	B	B
App. G III.D	Amend	Control and Tracking.	B	B
Appendix H	New	Alternative Dosimetry Methods Acceptable for Use to Demonstrate Compliance with NRC's Standards for Protection Against Radiation	-	B

* Consistent with 10 CFR 20.1401(a), the criteria in 10 CFR part 20, subpart E do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities.

Adequacy and Compatibility Table for 10 CFR Part 34

Section	Change	Subject	Compatibility	
			Existing	New
34.3	Delete	Definitions – ALARA	[A]	-
34.42(c), (d)	Delete	Radiation Safety Officer for industrial radiography.	D	-

Adequacy and Compatibility Table for 10 CFR Part 35

Section	Change	Subject	Compatibility	
			Existing	New
35.2	New	Definitions – Administration Regimen	-	B
35.2	New	Definitions – Caregiver	-	B
35.75(a)	Revised	Release of individuals containing unsealed byproduct material or implants containing	C	C

		byproduct material.		
35.75(b)	Amend	Release of individuals containing unsealed byproduct material or implants containing byproduct material.	C	B
35.75(c)	Amend	Release of individuals containing unsealed byproduct material or implants containing byproduct material.	C	C
35.75(d)	Amend	Release of individuals containing unsealed byproduct material or implants containing byproduct material.	D	D
35.2075	Amend	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.	D	D

Adequacy and Compatibility Table for 10 CFR Part 40

Section	Change	Subject	Compatibility	
			Existing	New
Appendix A	Amend	Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content.	Definitions - A for States with authority to regulate uranium mill activities (11e.(2) byproduct material) Criterion 11A.thru F and Criterion 12 are NRC. All of the remaining portions of the section are C-for States with authority to regulate uranium mill activities D- States without authority	Definitions -A for States with authority to regulate uranium mill activities (11e.(2) byproduct material) Criterion 5 and 6 are B -for States with authority to regulate uranium mill activities D- States without authority. Criterion 11A.thru F and Criterion 12 are NRC. All of the

				remaining portions of the section are C-for States with authority to regulate uranium mill activities D- States without authority

Adequacy and Compatibility Table for 10 CFR Part 61

Section	Change	Subject	Compatibility	
			Existing	New
61.41	Amend	Protection of the general population from releases of radioactivity.	A	A
61.43	Amend	Protection of individuals during operations.	H&S	H&S

Adequacy and Compatibility Table for 10 CFR Part 71

Section	Change	Subject	Compatibility	
			Existing	New
71.87	Amend	Routine determinations.	[B]	[B]

The NRC invites comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Management Directive 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs,” and its Handbook for more information. The NRC notes that, like the rule text, the compatibility category designations can change between the proposed rule and final rule, based on comments received and NRC decisions regarding the final rule. The NRC encourages anyone interested in commenting on the compatibility category designations in any manner to do so during the comment period.

XV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC is proposing to amend its regulations that govern its standards for protection against radiation. The amendments reflect the agency's reconsideration of its use of the LNT model for assessing health effects from radiation exposure and its application of the ALARA principle that is predicated on the LNT model. The proposed rule would reflect the NRC's experience and other developments in the field of radiation protection since the NRC's last major revisions to these standards in 1991. As part of the proposed rule, the NRC would discontinue the use of ALARA terminology in its regulations and guidance and would use a graded approach to dose management in its place.

The proposed rule would give licensees the option to voluntarily use alternative dosimetry methods to demonstrate compliance with NRC regulations in 10 CFR part 20 without separate NRC approval through a new regulation, § 20.1010, and its associated Appendix H. The NRC has determined that allowing the use of dosimetry methods based on specific, identified publications will offer flexibility to licensees and applicants, increase efficiency in licensing, operations, and administration of radiation protection programs, and bring the NRC's radiation protection framework more in line with current recommendations, while still retaining reasonable assurance of adequate protection of the public health and safety. The NRC determined that this change would maintain the effectiveness of the radiation protection regulatory framework because the alternative dosimetry methods that would be preapproved for use are appropriate for the scope of activities subject to 10 CFR part 20, are technically adequate and have been published by expert, standards-setting organizations, and provide sufficient transparency regarding

associated assumptions and uncertainties. Accordingly, the proposed new regulation, § 20.1010, would reference a listing of preapproved alternative dosimetry methods in proposed new Appendix H and it would also provide the criteria for the NRC approval of a method not listed in Appendix H. The methods to be included in Appendix H have been promulgated primarily by the ICRP, but the listing of approved methods also includes other methods published by consensus-setting organizations. In the future, the NRC expects to update Appendix H as appropriate, including as more methods become available.

In this proposed rule, the NRC is proposing to incorporate by reference the following voluntary consensus standards from the American National Standards Institute/American Nuclear Society (ANSI/ANS) and the International Commission on Radiological Protection (ICRP):

1. ANSI/ANS-6.1.1-2020 - ANSI/ANS, 2020. *Photon and Neutron Fluence-to-Dose Conversion Coefficients*. ANSI/ANS-6.1.1-2020. La Grange Park, IL: American Nuclear Society.
2. ICRP Publication 56 - ICRP, 1990*. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1*. ICRP Publication 56. Ann. ICRP 20 (2).
3. ICRP Publication 67 - ICRP, 1993*. Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients. ICRP Publication 67. Ann. ICRP 23 (3-4)*.
4. ICRP Publication 68 - ICRP, 1994. *Dose Coefficients for Intakes of Radionuclides by Workers.* ICRP Publication 68. Ann. ICRP 24 (4).
5. ICRP Publication 69 - ICRP, 1995. *Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 3 Ingestion Dose Coefficients*. ICRP Publication 69. Ann. ICRP 25 (1).

6. ICRP Publication 71 - ICRP, 1995. *Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients*. ICRP Publication 71. Ann. ICRP 25 (3-4).
7. ICRP Publication 72 - ICRP, 1995. *Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients*. ICRP Publication 72. Ann. ICRP 26 (1).
8. ICRP Publication 116 - ICRP, 2010. *Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures*. ICRP Publication 116. Ann. ICRP 40(2–5).
9. ICRP Publication 130 - ICRP, 2015. *Occupational Intakes of Radionuclides: Part 1*. ICRP Publication 130. Ann. ICRP 44(2).
10. ICRP Publication 134 - ICRP, 2016. *Occupational Intakes of Radionuclides: Part 2*. ICRP Publication 134. Ann. ICRP 45(3/4), 1–352.
11. ICRP Publication 137 - ICRP, 2017. *Occupational Intakes of Radionuclides: Part 3*. ICRP Publication 137. Ann. ICRP 46(3/4).
12. ICRP Publication 141 - ICRP, 2019. *Occupational Intakes of Radionuclides: Part 4*. ICRP Publication 141. Ann. ICRP 48(2/3).
13. ICRP Publication 144 - ICRP, 2020. *Dose Coefficients for External Exposures to Environmental Sources*. ICRP Publication 144. Ann. ICRP 49(2).
14. ICRP Publication 151 - ICRP, 2022. *Occupational Intakes of Radionuclides: Part 5*. ICRP Publication 151. Ann. ICRP 51(1–2).

The NRC invites comment on the applicability and use of other standards.

XVI. Incorporation by Reference—Reasonable Availability to Interested Parties

The NRC proposes to incorporate by reference. As described in the "Background" and "Discussion" sections of this document, these materials contain standards.

The NRC is required by law to obtain approval for incorporation by reference from the Office of the Federal Register (OFR). The OFR's requirements for incorporation by reference are set forth in 1 CFR part 51. On November 7, 2014, the OFR adopted changes to its regulations governing incorporation by reference (79 FR 66267). The OFR regulations require an agency to include in a proposed rule a discussion of the ways that the materials the agency proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties. The discussion in this section complies with the requirement for proposed rules as set forth in 1 CFR 51.5(a)(1).

The NRC considers "interested parties" to include all potential NRC stakeholders, not only the individuals and entities regulated or otherwise subject to the NRC's regulatory oversight. These NRC stakeholders are not a homogenous group but vary with respect to the considerations for determining reasonable availability. Therefore, the NRC distinguishes between different classes of interested parties for the purposes of determining whether the material is "reasonably available." The NRC considers the following to be classes of interested parties in NRC rulemakings with regard to the material to be incorporated by reference:

1. Individuals and small entities regulated or otherwise subject to the NRC's regulatory oversight (this class also includes applicants and potential applicants for licenses and other NRC regulatory approvals) and who are subject to the material to be incorporated by reference by rulemaking. In this context, "small entities" has the same meaning as a "small entity" under 10 CFR 2.810.

2. Large entities otherwise subject to the NRC's regulatory oversight (this class also includes applicants and potential applicants for licenses and other NRC regulatory approvals) and who are subject to the material to be incorporated by reference by rulemaking. In this context, “large entities” are those that do not qualify as a “small entity” under 10 CFR 2.810.
3. Non-governmental organizations with institutional interests in the matters regulated by the NRC.
4. Other Federal agencies, States, and local governmental bodies (within the meaning of 10 CFR 2.315(c)).
5. Federally-recognized and State-recognized Indian Tribes.
6. Members of the public (i.e., individual, unaffiliated members of the public who are not regulated or otherwise subject to the NRC's regulatory oversight) who may wish to gain access to the materials that the NRC proposes to incorporate by reference by rulemaking in order to participate in the rulemaking process.

ICRP documents are publicly available and may be found by contacting *International Commission on Radiological Protection*, 350 Albert Street Suite 410, Ottawa, Ontario, K1R 1A4, Canada or online at https://www.icrp.org/index.asp.

Interested parties may purchase a copy of the ANSI/ANS material from ANSI/ANS at *American National Standards Institute/American Nuclear Society (ANSI/ANS)*: ATTN Standards, 555 N. Kensington Avenue, La Grange Park, IL 60526, or at the ANSI website https://webstore.ansi.org/. The purchase price for the material is $97.

For the class of interested parties constituting members of the public who wish to gain access to the materials to be incorporated by reference in order to participate in the rulemaking, the NRC recognizes that the cost may be so high that the materials could be regarded as not reasonably available for purposes of commenting on this proposed rule,

despite the NRC's actions to make the materials available at the NRC's PDR. Accordingly, the NRC requested that ANSI/ANS consider enhancing public access to these materials during the public comment period. On February 11, 2026, ANSI/ANS agreed to make the material available online in a read-only electronic access format during the public comment period. Therefore, the one ANSI/ANS document that the NRC proposes to incorporate by reference in this rulemaking is available in read-only format at the ANSI/ANS website *https://go.asme.org/NRC-ASME*.

In addition, as described in Section XVIII of this document, documents related to this proposed rule are available online in the NRC's ADAMS Public Documents Collection at https://www.nrc.gov/reading-rm/adams.html.

The materials are available to all interested parties in multiple ways and in a manner consistent with their interest in this proposed rule. Therefore, the NRC concludes that the materials the NRC proposes to incorporate by reference in this proposed rule are reasonably available to all interested parties.

XVII. Executive Orders

The following are Executive Orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (as amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action. Accordingly, the NRC submitted this proposed rule to OIRA for review. The NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in Section IX of this document, "Regulatory Analysis."

B. Executive Order 14154: Unleashing American Energy

The NRC has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is tentatively determined to be a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule can be found in Section IX of this document, “Regulatory Analysis.”

D. Executive Order 14267: Reducing Anti-Competitive Regulatory Barriers

E.O. 14267 requires the NRC to identify anti-competitive regulations for recission or modification. The NRC identified § 20.1101 because of the burden imposed by the NRC’s implementation of the ALARA standard. The proposed modification of this and related regulations supports the objectives of E.O. 14267 by modifying regulatory requirements that could “create unnecessary barriers to entry for new market participants” or “limit competition between competing entities or have the effect of limiting competition between competing entities.”

E. Executive Order 14270: Zero-Based Regulatory Budgeting to Unleash American Energy

E.O. 14270 requires the NRC to insert a conditional sunset date into all new or amended NRC regulations provided the regulations are (1) promulgated under the Atomic Energy Act of 1954, as amended (AEA), the Energy Reorganization Act of 1974, as amended (ERA), and the Nuclear Waste Policy Act of 1982, as amended (NWPA); (2) not statutorily required; and (3) not part of the NRC’s permitting regime. The NRC determined that the regulatory changes proposed in this rule are part of the NRC’s permitting regime authorized by the AEA, ERA, or NWPA. Therefore, the NRC views this rulemaking to be outside the scope of E.O. 14270 and did not insert conditional sunset dates for the regulatory changes in this proposed rule.

F. Executive Order 14294: Fighting Overcriminalization in Federal Regulations

This proposed rule includes Federal regulations that, if adopted, would be enforceable by criminal penalty, as authorized by Section 223 of the Atomic Energy Act of 1954, as amended (AEA). Therefore, per E.O. 14294, those regulations constitute "criminal regulatory offenses."

For the purposes of Section 223 of the AEA, the NRC is issuing this proposed rule that would amend 10 CFR parts 19, 20, 34, 35, 40, 50, 53, 61, 71, and 72 under one or more of Sections 161b, 161i, or 161o of the AEA, except as noted in §§ 19.40(b), 20.2402(b), 34.123(b), 35.4002(b), 40.82(b), 50.111(b), 53.9010(b), 61.84(b), 71.100(b), and 72.86(b). The applicability of criminal penalties to regulations in parts 19, 20, 34, 35, 40, 50, 53, 61, 71, and 72 is set forth in §§ 19.40, 20.2402, 34.123, 35.4002, 40.82, 50.111, 53.9010, 61.84, 71.100, and 72.86. Willful violations of the 10 CFR parts 19, 20, 34, 35, 40, 50, 53, 61, 71, and 72 regulations, other than those listed in §§ 19.40(b), 20.2402(b), 34.123(b), 35.4002(b), 40.82(b), 50.111(b), 53.9010(b), 61.84(b), 71.100(b), and 72.86(b) (including as updated by this proposed rule), would be subject to criminal enforcement.

XVIII. 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 / *FEDERAL REGISTER* CITATION
Rule Related Documents	
Draft Environmental Assessment for the Proposed Rule—Executive Order 14300: Reforming and Modernizing the NRC's Radiation Protection Framework	ML26180A026
Draft Regulatory Analysis for the Proposed Rule—Executive Order 14300: Reforming and Modernizing the NRC's Radiation Protection Framework	ML26180A025
Draft Supporting Statement for the Proposed	ML25337A399

Rule—Executive Order 14300: Reforming and Modernizing the NRC's Radiation Protection Framework	
Proposed Rule – Burden Table for Reforming and Modernizing the NRC's Radiation Protection Framework	ML26007A106
Unofficial Redline for the Proposed Rule—Executive Order 14300: Reforming and Modernizing the NRC's Radiation Protection Framework	ML26180A027
LNT/ALARA Related Documents	
Title 10 – Atomic Energy, Chapter I – Atomic Energy Commission, Part 20 – "Standards for Protection Against Radiation," January 29, 1957	22 FR 549
Title 40 – Protection of Environment, Chapter I – Environmental Protection Agency, Subchapter F – Radiation Protection Programs, [FRL 659-6], Part 190 – "Environmental Radiation Protection Standards for Nuclear Power Operations," January 13, 1977	42 FR 2858
Proposed Rule, "Standards for Protection Against Radiation; Republication," January 9, 1986	51 FR 1092
Proposed Rule and Notice of Public Hearing, "National Emission Standards for Hazardous Air Pollutants; Regulation of Radionuclides," March 7, 1989	54 FR 9612
Final Rule and Notice of Reconsideration, "National Emission Standards for Hazardous Air Pollutants; Radionuclides," December 15, 1989	54 FR 51654
Final Rule, "Standards for Protection Against Radiation," May 21, 1991	56 FR 23360
Executive Order 12866, "Regulatory Planning and Review," October 4, 1993	58 FR 51735
Final Rule, "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," December 10, 1996	61 FR 65120
Final Rule, "Radiological Criteria for License Termination," July 21, 1997	62 FR 39058
"Plain Language in Government Writing," June 10, 1998	63 FR 31885
Final Rule, "Respiratory Protection and Controls to Restrict Internal Exposures," October 7, 1999	64 FR 54543
Advanced Notice of Proposed Rulemaking, "Radiation Protection," July 25, 2014	79 FR 43284
"Incorporation by Reference," November 7, 2014	79 FR 66267
Petition for Rulemaking; Notice of Docketing and Request for Comment, "Linear No-Threshold Model and Standards for Protection Against Radiation," June 23, 2015	80 FR 35870
"Rulemaking Activities Being Discontinued by the NRC," December 28, 2016	81 FR 95410

“Agreement State Program Policy Statement,” October 18, 2017	82 FR 48535
“Linear No-Threshold Model and Standards for Protection Against Radiation,” August 17, 2021	86 FR 45923
Executive Order 14154, “Unleashing American Energy,” January 29, 2025	90 FR 8353
Executive Order 14156, “Declaring a National Energy Emergency,” January 29, 2025	90 FR 8433
Executive Order 14192, “Unleashing Prosperity Through Deregulation,” February 6, 2025	90 FR 9065
Executive Order 14215, “Ensuring Accountability for All Agencies,” February 24, 2025	90 FR 10447
Executive Order 14267, “Reducing Anti-Competitive Regulatory Barriers,” April 15, 2025	90 FR 15629
Executive Order 14270, “Zero-Based Regulatory Budgeting to Unleash American Energy,” April 15, 2025	90 FR 15643
Executive Order 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” May 29, 2025	90 FR 22587
Executive Order 14303, “Restoring Gold Standard Science,” May 29, 2025	90 FR 22601
“2025 Draft List of Critical Minerals,” August 26, 2025	90 FR 41591
International Atomic Energy Agency (IAEA) Nuclear Safety and Security Glossary	https://www.iaea.org/publications/15236/iaea-nuclear-safety-and-security-glossary#
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The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at https://www.regulations.gov under Docket ID NRC-2025-1140. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC-2025-1140); (2) click the "Subscribe" link; and (3) enter an email address and click on the "Subscribe" link.

List of Subjects

10 CFR part 19

Criminal penalties, Environmental protection, Nuclear Energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR part 20

Byproduct material, Criminal penalties, Hazardous waste, Incorporation by reference; Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste manifest.

10 CFR part 34

Criminal penalties, Incorporation by reference, Manpower training programs, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures, X-rays.

10 CFR part 35

Biologics, Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR part 40

Criminal penalties, Exports, Government contracts, Hazardous materials

transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, Inspection, Intergovernmental relations, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR part 61

Criminal penalties, Hazardous waste, Indians, Intergovernmental relations, Low- level waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Waste treatment and disposal, Whistleblowing. protection of the general population from releases of radioactivity, Protection of individuals during operations.

10 CFR part 71

Criminal penalties, Hazardous materials transportation, Intergovernmental

relations, Nuclear materials, Packaging and containers, Penalties, Radioactive materials, Reporting and recordkeeping requirements.

10 CFR part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 19, 20, 34, 35, 40, 50, 53, 61, 71, and 72:

PART 19—NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

1. The authority citation for part 19 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 211, 401 (42 U.S.C. 5841, 5851, 5891); 44 U.S.C. 3504 note.

2. In § 19.12, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 19.12 Instruction to workers.

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of the limit for individual members of the public in § 20.1301(a)(1) of this chapter shall be—

(1) * * *

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to manage dose, and

in the purposes and functions of protective devices employed;

* * * * *

3. In § 19.13, revise paragraph (b)(1) to read as follows:

§ 19.13 Notifications and reports to individuals.

* * * * *

(b) * * *

(1) The individual's occupational dose exceeds the limit for individual members of the public in § 20.1301(a)(1) of this chapter; or

* * * * *

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

4. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161,170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

5. In § 20.1003,

(a) revise the definitions of “Airborne radioactivity area”, “Annual limit on intake”, “Committed dose equivalent”, “Committed effective dose equivalent”, “Derived air concentration”, “Dose or radiation dose”, “Dose equivalent”, “Effective dose equivalent”, “License”, “Nonstochastic effect”, “Quarter”, “Stochastic effects”, and “Weighting factor”;

(b) add, in alphabetical order, definitions for “Committed effective dose”, “Committed equivalent dose”, “Dosimetry method (or system)”, “Effective dose”, “Equivalent dose”, “Graded approach to dose management”, “Planned occupational dose limit extension”, “Radiation weighting factor”, and “Total Effective Dose”; and

(c) remove the definition for the term “ALARA”.

The additions and revisions read as follows:

§ 20.1003 Definitions.

* * * * *

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to §§ 20.1001-20.2402, or as developed using alternative dosimetry methods pursuant to § 20.1010, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

* * * * *

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in table 1, columns 1 and 2, of appendix B to §§ 20.1001-20.2402; alternatively, licensees can develop ALI values using alternative dosimetry methods pursuant to § 20.1010).

* * * * *

Committed dose equivalent ($H_{T,Q,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

* * * * *

Committed effective dose (E_t) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed equivalent dose to these organs or tissues ($E_t = \Sigma\ w_T\ H_{T,t}$).

* * * * *

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma\ w_T\ H_{T,Q,50}$).

* * * * *

Committed equivalent dose ($H_{T,t}$) means the equivalent dose to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the years (t) period following the intake. “t” is 50 years for adults and 70 years for minors.

* * * * *

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in table 1, column 3, of appendix B to §§ 20.1001-20.2402; alternatively, licensees can develop DAC values using alternative dosimetry methods pursuant to § 20.1010.

* * * * *

Dose or *radiation dose* is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, committed equivalent dose, committed effective dose, total effective dose equivalent, effective dose, or total effective dose, as defined in other paragraphs of this section.

Dose equivalent ($H_{T,Q}$) means the product of the absorbed dose in tissue, quality

factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimetry method (or system) means an approach for calculating the biological effects of ionizing radiation exposure in humans. The approach provides a repeatable method of converting from fundamental knowledge of radioactive decay to biological effects, typically through modeling and a series of conversion and correction factors for types of radiation emitted and interactions with tissues, organs, and the environment.

* * * * *

Effective dose (E) is the sum of the products of the equivalent dose (H_T) to a tissue or organ and the tissue weighting factor for that tissue or organ (w_T). The sum is performed over all the specified organs and tissues involved and includes equivalent doses from external sources and equivalent doses (committed) for intakes of radionuclides ($E = \Sigma\ w_T\ H_T$). Effective dose is applicable only to stochastic effects and the tissue weighting factors were developed for a reference population of equal numbers of both males and females and a wide range of ages.

Effective dose equivalent (H_E) is the sum of the products of the dose equivalent to the organ or tissue ($H_{T,Q}$) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\ w_T\ H_{T,Q}$).

* * * * *

Equivalent dose (H_T) is the product of the absorbed dose averaged over a tissue or organ and the radiation weighting factor for the radiation under consideration; therefore, it is an absorbed dose that is weighted for the radiation quality of interest. The equivalent dose term was introduced in International Commission on Radiological Protection Publication 60 to differentiate dose equivalent, which depends on the quality factor for weighting, from a new weighted absorbed dose value, which depends on the radiation weighting factor (w_R). The units of equivalent dose are the rem and sievert (Sv).

* * * * *

Graded approach to dose management means an approach whereby progressively increasing radiation protection measures are required as prospective, or actual, radiation doses exceed determinate thresholds to provide reasonable assurance that the applicable regulatory limit is not exceeded.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 52, 53, 60, 61, 63, 70, or 72 of this chapter.

* * * * *

Nonstochastic effect (also called a deterministic effect or tissue effect) means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist.

* * * * *

Planned occupational dose limit extension means a planned exposure to radiation in addition to the annual occupational dose limits that utilizes unused occupational dose allowances from previous years. Such exposure must be limited so that the total occupational dose received by the individual for the current year and the preceding four years does not exceed limits prescribed in this part.

* * * * *

Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

* * * * *

Radiation weighting factor (w_R) is a modifying factor that represents the type and energy of the radiation incident on the body or, when sources are within the body, the

type and energy emitted by the source.

* * * * *

Stochastic effects means malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold, for radiation protection purposes.

* * * * *

Total Effective Dose (TED) means the sum of the effective dose (for external exposures) and the committed effective dose (for internal exposures). Values of TEDE and TED can be added (e.g., for the purpose of long-term dose tracking) when using different dosimetry systems, provided they are developed in accordance with dosimetry methods or systems as defined in this part.

* * * * *

Weighting factor w_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. Licensees can obtain w_T values using alternative dosimetry methods pursuant to § 20.1010. For calculating the effective dose equivalent, the values of w_T are:

* * * * *

6. In § 20.1004, add paragraphs (d) and (e) to read as follows:

§ 20.1004 Units of radiation dose.

* * * * *

(d) In cases where a licensee or applicant uses alternative dosimetry methods pursuant to § 20.1010, the applicable conversion factors between absorbed dose and equivalent dose may be determined using the standards in appendix H or methods approved through § 20.1010(b).

(e) Dosimetric quantities that are determined using different dosimetry methods can be added as follows-

(1) Values of equivalent dose and dose equivalent that are determined using different dosimetry methods are additive provided that the methods used in their determination are applied as intended.

(2) Values of total effective dose equivalent/effective dose equivalent and total effective dose/effective dose that are determined using different dosimetry methods are additive provided that the methods used in their determination are applied as intended.

(3) Notwithstanding § 20.1004(e)(1) and § 20.1004(e)(2), where a licensee or applicant uses weighting factors (i.e., w_R or w_T) that differ from those published by the International Commission on Radiological Protection for a particular dosimetry method, the resulting quantities are not additive to values that are determined using International Commission on Radiological Protection methods. In these cases, these resulting dosimetric quantities are subject to the conditions, including those on additivity, as specified in the corresponding NRC approval of that dosimetry method.

7. Add § 20.1010 to subpart A to read as follows:

§ 20.1010 Alternative dosimetry methods.

The regulations in this part are largely based on dosimetry methods that implement the recommendations of International Commission on Radiological Protection Publication 26 and supporting documents (e.g., International Commission on Radiological Protection Publication 30).

(a) A licensee or applicant may use alternative dosimetry methods, including assumptions (e.g., aerosol size distribution, solubility class, density, and chemical forms), dose conversion factors, and tissue and radiation weighting factors, to demonstrate compliance with the dose limits in subparts C and D, as well as other dose-

based requirements and criteria in this part, and to develop derived limits such as ALIs and DACs. Unless otherwise approved by the NRC per paragraph (b), alternative dosimetry methods must be consistent with one or more of the standards incorporated by reference and listed in appendix H to part 20.

(b) A licensee or applicant may apply for NRC authorization to use an alternative dosimetry method not listed in appendix H to part 20. The licensee or applicant shall include the following information in this application—

(1) Justification that the proposed method is appropriate for, or applicable to, the intended use;

(2) Description of the technical adequacy of the proposed method, for example, as supported by peer-reviewed research or consensus-based standards; and

(3) Demonstration that the proposed method provides transparency regarding assumptions and uncertainties such that a knowledgeable third-party could apply the method and obtain results similar to those obtained by the licensee or applicant.

8. In § 20.1101, revise paragraphs (b) through (d) to read as follows:

§ 20.1101 Radiation protection programs.

* * * * *

(b) The licensee shall use procedures, engineering controls, and a graded approach to dose management based upon sound radiation protection principles to maintain occupational doses and doses to members of the public within the limits specified in this part.

(c) The licensee shall periodically review the radiation protection program content and implementation.

(d) Notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its

daughters, shall be established by licensees other than those subject to § 50.34a or § 53.260 of this chapter, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 25 mrem (0.25 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence. A licensee or applicant may request prior NRC authorization to establish a higher constraint, provided that the proposed constraint provides an ample margin of safety to protect public health.

9. Revise and republish § 20.1201(a) through (d) to read as follows:

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned occupational dose limit extensions under § 20.1205 and planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of—

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, with the exception of doses

received under § 20.1205, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC or by an alternative dosimetry method pursuant to § 20.1010. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits. Alternatively, the licensee may use alternative dosimetry methods to demonstrate compliance with the occupational dose limits (see § 20.1010).

* * * * *

10. In § 20.1202, revise footnote 1 to read as follows:

§ 20.1202 Compliance with requirements for summation of external and internal doses.

* * * * *

[1] An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, w_T, and the committed dose equivalent, $H_{T,Q,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,Q,50}$, (*i.e.*, W_T $H_{T,Q,50}$) per unit intake for any organ or tissue.

11. In § 20.1204, revise paragraphs (c)(2) and (3), (e)(1), and (h)(2), to read as follows:

§ 20.1204 Determination of internal exposure.

* * * * *

(c) * * *

(2) Upon prior approval of the Commission or consistent with the use of alternative dosimetry methods to demonstrate compliance with dose limits as allowed by § 20.1010, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

(3) If applicable, separately assess the contribution of fractional intakes of different solubility classes (e.g., Class D, W, or Y compounds of a given radionuclide (see appendix B to part 20)) to the committed effective dose equivalent.

* * * * *

(e) * * *

(1) The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from appendix B to part 20, or as determined using an alternative dosimetry method as allowed by § 20.1010, for each radionuclide in the mixture; or

* * * * *

(h) * * *

(2) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the

licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in § 20.1201(a)(1)(ii) is met. Table 1 of appendix B to part 20 lists stochastic ALIs, even when the limiting ALI and DAC is governed by the nonstochastic organ dose limit of 50 rem (0.5 Sv). In cases where a licensee is using an alternative dosimetry method pursuant to § 20.1010, that licensee can develop the stochastic ALI to use for the purposes of this paragraph.

12. Add section § 20.1205 to subpart C to read as follows:

§ 20.1205 Planned occupational dose limit extension.

A licensee may authorize a worker that is not a declared pregnant woman or a minor to receive occupational doses in excess of the limits specified in § 20.1201 provided that each of the following conditions is satisfied—

(a) The licensee (and employer if the employer is not the licensee) authorizes the planned occupational dose limit extension, in writing, before the dose limit specified in § 20.1201 is exceeded.

(b) Before a planned occupational dose limit extension, the licensee ensures that the individuals involved are—

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and estimated radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to manage doses considering other risks that may be present.

(c) Prior to permitting an individual to participate in a planned occupational dose limit extension, the licensee ascertains prior occupational doses as required by § 20.2104(b) during the current year and the preceding four years for each individual involved.

(d) The licensee does not authorize a planned occupational dose limit extension that would cause an individual to receive a dose from all occupational exposures in excess of—

(1) Five times the numerical limits in § 20.1201(a)(1) and § 20.1201(a)(2)(ii) over the current year and the preceding four years;

(2) Twice the numerical limits in § 20.1201(a)(1) and § 20.1201(a)(2)(ii) in any one year; and

(3) A lens dose equivalent of 15 rem (0.15 Sv) in any one year.

(e) The licensee maintains records of the conduct of a planned occupational dose limit extension in accordance with § 20.2105.

(f) The dose from planned occupational dose limit extensions is not to be considered in controlling future occupational dose of the individual under § 20.1201(a) but is to be included in evaluations required by §§ 20.1205 (c) and (d) and 20.1206 (d) and (e).

13. In § 20.1206, revise paragraph (c)(3) to read as follows:

§ 20.1206 Planned special exposures.

* * * * *

(c) * * *

(3) Instructed in the measures to be taken to manage doses considering other risks that may be present.

* * * * *

14. In § 20.1301, revise paragraph (a)(1), remove and reserve paragraph (a)(2), and revise paragraphs (b) through (d) to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(1) The total effective dose equivalent to individual members of the public from the licensed operation, or any other source of radiation under the control of a licensee, does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions 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, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003.

(2) [Reserved]

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals. Alternatively, a licensee or applicant may request prior NRC authorization for an annual dose limit in excess of 0.1 rem (1 mSv) for members of the public who have access to controlled areas, provided that dose is appropriately managed.

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit members of the public to visit an individual who cannot be released, under § 35.75, to receive a radiation dose in excess of 0.1 rem (1 mSv) if—

(1) The radiation dose received is not likely to exceed either—

(i) 0.5 rem (5 mSv) for a member of the public who is not a caregiver per administration regimen; or

(ii) 2 rem (20 mSv) for a caregiver, as defined in 10 CFR part 35, per administration regimen; and

(2) The authorized user, as defined in 10 CFR part 35, has determined before the visit that it is appropriate.

(d) A licensee or applicant may apply for prior NRC authorization to operate with an annual dose limit for an individual member of the public in excess of 0.1 rem (1 mSv). The licensee or applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section;

(2) Description of the licensee's program to assess and control dose within the proposed dose limit for an individual member of the public; and

(3) The proposed dose limit for an individual member of the public and its supporting basis, including why it remains protective of the public health and safety.

* * * * *

15. In § 20.1302, revise paragraph (b)(2) and remove and reserve paragraph (c) to read as follows:

§ 20.1302 Compliance with dose limits for individual members of the public.

* * * * *

(b) * * *

(1) * * *

(2) Demonstrating that—

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of appendix B to part 20 or as developed using alternative dosimetry methods pursuant to § 20.1010; and

(ii) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.05 rem (0.5 mSv) in a year.

(c) [Reserved]

16. Revise § 20.1402 to read as follows:

§ 20.1402 Radiological criteria for unrestricted use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to the

average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and, consistent with § 20.1406(c), the residual radioactivity has been reduced to levels where further reductions would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal.

17. In § 20.1403, revise paragraph (a) and revise and republish paragraph (e) to read as follows:

§ 20.1403 Criteria for license termination under restricted conditions.

* * * * *

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of § 20.1402 would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal; would result in net public or environmental harm; or would not be justified through a cost-benefit analysis;

* * * * *

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group would not exceed either—

(1) 100 mrem (1 mSv) per year provided that the licensee—

Demonstrates that further reductions in residual radioactivity would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal**;** or

(2) 500 mrem (5 mSv) per year provided that the licensee—

(i) Demonstrates that further reductions in residual radioactivity necessary to

comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of § 20.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph (c) of this section.

18. In § 20.1404, revise and republish paragraphs (a)(1) through (a)(4) to read as follows:

§ 20.1404 Alternate criteria for license termination.

(a) * * *

(1) Provides assurance that public health and safety would continue to be protected by submitting an analysis demonstrating that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than 100 mrem/y (1 mSv/y);

(2) Has employed to the extent practical restrictions on site use according to the provisions of § 20.1403 in minimizing exposures at the site;

(3) Demonstrates that further reductions in residual radioactivity would not be justified when considering any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to

the Commission indicating the licensee's intent to decommission in accordance with §§ 30.36(d), 40.42(d), 50.82(a) and (b), subpart G of part 53, 70.38(d), or 72.54 of this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues; and

* * * * *

19. In § 20.1405, revise paragraph (b) to read as follows:

§ 20.1405 Public notification and public participation.

* * * * *

(b) Publish a notice in the Federal Register and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

20. In § 20.1502, revise introductory text and paragraphs (a)(4) and (b)(1) to read as follows:

§ 20.1502 Conditions requiring individual monitoring of external and internal

occupational dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part.

(a) * * *

(4) Individuals entering a high or very high radiation area. These individuals shall be monitored for external occupational dose, unless any of the conditions of § 20.1502(b) apply, in which case they shall be monitored for both external and internal occupational dose.

(b) * * *

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, columns 1 and 2, of appendix B to §§ 20.1001-20.2402 or as developed using alternative dosimetry methods pursuant to § 20.1010;

* * * * *

§ 20.1601 [Amended]

21. In § 20.1601(f), remove the text “ALARA”.

22. Revise and republish § 20.1702 to read as follows:

§ 20.1702 Use of other controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall increase monitoring and limit intakes by one or more of the following means—

(1) Control of access;

(2) Limitation of exposure times;

(3) Use of respiratory protection equipment; or

(4) Other controls.

(b) If the licensee performs an analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

23. In § 20.1703, revise paragraph (b) to read as follows:

§ 20.1703 Use of individual respiratory protection equipment.

* * * * *

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the NRC for authorized use of this equipment except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information. The use of equipment that has not been tested or certified by NIOSH, but has previously been approved for use by the NRC, does not require an application and its approval as described in this paragraph, provided that the licensee maintains an evaluation to demonstrate that the bases for the previous NRC approval—as documented in the applicable safety evaluation—are applicable to the licensee's facility.

*** * * * ***

§ 20.1704 [Amended]

24. In § 20.1704(a), remove the text “ALARA” and add in its place, “within the requirements of this part”.

25. In § 20.1705, add paragraph (c) to read as follows:

§ 20.1705 Application for use of higher assigned protection factors.

* * * * *

(c) The use of higher assigned protection factors that have previously been approved for use by the Commission does not require an application and its approval as described in this section, provided that the licensee maintains an evaluation to demonstrate that the bases for the previous Commission approval—as documented in the applicable safety evaluation—are applicable to the licensee's facility.

26. In § 20.1905, revise paragraph (b) to read as follows:

§ 20.1905 Exemptions to labeling requirements.

* * * * *

(b) Containers holding licensed material in concentrations less than those specified in table 3 of appendix B to part 20 or concentrations derived using alternative dosimetry methods pursuant to § 20.1010; or

* * * * *

§ 20.2002 [Amended]

27. In § 20.2002(d), remove the text “ALARA and”.

28. In § 20.2003, revise paragraphs (a)(2) and (a)(3)(i) to read as follows:

§ 20.2003 Disposal by release into sanitary sewerage.

(a) * * *

(1) * * *

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20 or concentrations derived using alternative dosimetry methods

pursuant to § 20.1010; and

(3) * * *

(i) The licensee shall determine the fraction of the limiting concentration in table 3 of appendix B to part 20, or the limiting concentrations derived using alternative dosimetry methods pursuant to § 20.1010, represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the applicable limiting concentration; and

* * * * *

§ 20.2004 [Amended]

29. In § 20.2004, remove from the first sentence in paragraph (b)(1) the text “the requirements of appendix I to part 50 of this chapter and”.

§ 20.2101 [Amended]

30. In § 20.2101, remove from paragraph (c) the text “Not withstanding” and replace with “Notwithstanding”.

31. In § 20.2104, revise paragraphs (b) and (e)(2) to read as follows:

§ 20.2104 Determination of prior occupational dose.

* * * * *

(b) Prior to permitting an individual to participate in a planned occupational dose limit extension or a planned special exposure, the licensee shall determine—

(1) For a planned occupational dose limit extension—

(i) Prior occupational doses during the current year and the preceding four years that correspond to the applicable limits in § 20.1205(d) for each individual involved.

(2) For a planned special exposure—

(i) The internal and external doses from all previous planned special exposures;

and

(ii) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

* * * * *

(e) * * *

(2) That the individual is not available for planned occupational dose limit extensions, if records for the current year and the preceding four years are not complete, and planned special exposures.

* * * * *

32. In § 20.2105:

a. Revise the section heading and paragraphs (a)(5) and (6);

b. Redesignate paragraph (b) as paragraph (c); and

c. Add a new paragraph (b).

The revisions and addition read as follows:

§ 20.2105 Records of planned occupational dose limit extensions and planned special exposures.

(a) * * *

(1) * * *

(5) How doses were managed; and

(6) The doses received by individuals involved in the planned special exposure.

(b) For each use of the provisions of § 20.1205 for planned occupational dose limit extensions, the licensee shall maintain records that describe the circumstances requiring the extension of occupational dose limits, how doses were managed, and the doses received by individuals involved in the planned occupational dose limit extension.

33. In § 20.2106, revise paragraph (a) introductory text and paragraphs (a)(5)

through (7) to read as follows:

§ 20.2106 Records of individual monitoring results.

(a) *Recordkeeping requirement*. Each licensee shall maintain records of doses received by individuals for whom monitoring was required pursuant to § 20.1502 and records of doses received during planned occupational dose limit extensions, planned special exposures, accidents, and emergency conditions. These records[5] must include, when applicable—

(1) * * *

(5) The total effective dose equivalent when required by § 20.1202;

(6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose; and

(7) In cases where monitoring was required pursuant to § 20.1502, but the dose received did not exceed 10 percent of the applicable monitoring criteria, the licensee may, instead of recording the numerical value of the dose received, annotate that an occupational dose was received but did not exceed the criteria for recording.

* * * * *

[5] Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

34. In § 20.2107, add paragraphs (c) and (d) to read as follows:

§ 20.2107 Records of dose to individual members of the public.

* * * * *

(c) The licensee shall retain a record of the justification for the dose received by a caregiver as described in § 20.1301(c)(1)(ii).

(d) The licensee shall retain the records required by paragraph (c) of this section for 3 years after the final date of the allowed exposure.

35. In § 20.2202, revise paragraph (e) to read as follows:

§ 20.2202 Notification of incidents.

* * * * *

(e) The provisions of this section do not include doses that result from planned occupational dose limit extensions or from planned special exposures that are within the limits for planned special exposures, and that are reported under § 20.2204.

36. In § 20.2203**:**

a. revise and republish paragraph (a)(2) and

b. remove the text “ALARA” from paragraph (b)(iv).

The revision reads as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

(a) *** * ***

(1) *** * ***

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in § 20.1201 unless they are exceeded pursuant to § 20.1205 or § 20.1206; except that reporting of unplanned exceedances of the limit in 20.1201(a)(1)(i) is required only if the total effective dose equivalent for the current year and the preceding four years exceeds 25 rem; or

(ii) The occupational dose limits for a minor in § 20.1207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or

(iv) The limits for an individual member of the public in § 20.1301, except that reporting of exceedances of the limit in § 20.1301(a) is required only if the total dose to a single individual for the current year and the preceding four years exceeds 500 mrem; or

(v) Any applicable limit in the license; or

(vi) The constraints for air emissions established under § 20.1101(d); or

(vii) The applicable dose limit for a planned occupational dose limit extension in § 20.1205(c); or

(viii) The applicable dose limit for a planned special exposure in § 20.1206(e); or

* * * * *

37. In appendix G to 10 CFR part 20:

a. Revise and republish the introductory paragraphs to Section I, add a definition for “Carrier”, remove the definition for “Computer readable medium”, and revise the definitions for “EPA identification number”, “High integrity container”, “NRC Forms 540, 540A, 541, 541A, 542, and 542A”, “Shipping paper”, and “Uniform Low-Level Radioactive Waste Manifest or uniform manifest”;

b. Revise paragraph III.A.6, paragraph III.B.4, paragraph III.C.7, and paragraph III.D.2., and amend paragraph III.E.1. to remove the text “or receipt” and add, in its place, “of receipt”.

The revisions read as follows:

Appendix G to Part 20—Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest (OMB Control Numbers 3150-0164,-0165, and-0166) reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive

Waste Manifest (Manifest Index and Regional Compact Tabulation)). The Manifest does not need to use these NRC Forms themselves as long as the Manifest reflects the information requested on the applicable NRC Forms. References to NRC Forms 540, 540A, 541, 541A, 542, and 542A in this appendix refer to either the NRC Form(s) or any other document(s) reflecting the information requested on the NRC Form(s) (e.g., licensee-generated versions of the NRC Forms).

Upon agreement between shipper and consignee, NRC Forms 540 and 540A, 541 and 541A, and 542 and 542A may be completed, signed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. NRC Forms 540 and 540A must be transmitted to the carrier in accordance with regulations of the Department of Transportation (DOT). Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, computer printouts, or electronic copies that reproduce the data of the uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001,

telephone (301) 415-5877, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

This appendix includes information requirements of the DOT, as codified in 49 CFR parts 172, 174, 175, 176, and 177. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency (EPA) regulations, as codified in 40 CFR parts 259, 261, or elsewhere, is not addressed in this section. However, any forms required by the EPA must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Carrier means a person who transports passengers or property in commerce by rail car, aircraft, motor vehicle, or vessel.

* * * * *

EPA identification number means the number received by a carrier following application to the Administrator of EPA as required by 40 CFR part 263.

* * * * *

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of § 61.56 of this chapter, and to meet DOT requirements for a Type A package.

* * * * *

NRC Forms 540, 540A, 541, 541A, 542, and 542A mean either the NRC Form(s) or any other document(s) reflecting the information requested on the NRC Form(s) (e.g., licensee-generated or Agreement State-generated versions of the NRC Forms).

* * * * *

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT regulations.

* * * * *

Uniform Low-Level Radioactive Waste Manifest or uniform manifest means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed.

* * * * *

III. Control and Tracking

A. * * *

6. If required by regulations of the DOT, physically include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

* * * * *

B. * * *

4. If required by regulations of the DOT, physically include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

* * * * *

C. * * *

7. If required by regulations of the DOT, physically include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

* * * * *

D. * * *

2. Maintain copies of or electronically store all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the Commission terminates the license; and

* * * * *

38. Add new Appendix H to part 20 to read as follows:

Appendix H to Part 20—Alternative Dosimetry Methods Acceptable for Use to Demonstrate Compliance with NRC's Standards for Protection Against Radiation

(a) The material listed in this appendix for developing alternative dosimetry methods is incorporated by reference into § 20.1010 with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) 1 CFR part 51. All approved material is available for inspection at the Nuclear Regulatory Commission (NRC) and at the National Archives Records Administration (NARA). Contact the NRC at NRC Technical Library, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-7000; email: Library.Resource@nrc.gov. For information on the availability of this material at NARA, visit https://www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov. The material may also be obtained from the following sources:

(1) ***American National Standards Institute/American Nuclear Society (ANSI/ANS),*** ATTN Standards, 555 N. Kensington Avenue, La Grange Park, IL 60526; https://webstore.ansi.org/.

(i) ANSI/ANS-6.1.1-2020, "Photon and Neutron Fluence-to-Dose Conversion Coefficients." IBR approved for § 20.1010(a).

(2) **International Commission on Radiological Protection (ICRP)**, 350 Albert Street Suite 410, Ottawa, Ontario, K1R 1A4, Canada; https://www.icrp.org/index.asp.

(i) ICRP Publication 56 - ICRP, 1990. "Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1." ICRP Publication 56. Ann. ICRP 20 (2). IBR approved for § 20.1010(a).

(ii) ICRP Publication 67 - ICRP, 1993. "Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients." ICRP Publication 67. Ann. ICRP 23 (3-4). IBR approved for § 20.1010(a).

(iii) ICRP Publication 68 - ICRP, 1994. “Dose Coefficients for Intakes of Radionuclides by Workers.” ICRP Publication 68. Ann. ICRP 24 (4). IBR approved for § 20.1010(a).

(iv) ICRP Publication 69 - ICRP, 1995. “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 3 Ingestion Dose Coefficients.” ICRP Publication 69. Ann. ICRP 25 (1). IBR approved for § 20.1010(a).

(v) ICRP Publication 71 - ICRP, 1995. “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients.” ICRP Publication 71. Ann. ICRP 25 (3-4). IBR approved for § 20.1010(a).

(vi) ICRP Publication 72 - ICRP, 1995. “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients.” ICRP Publication 72. Ann. ICRP 26 (1). IBR approved for § 20.1010(a).

(vii) ICRP Publication 116 - ICRP, 2010. “Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures.” ICRP Publication 116. Ann. ICRP 40(2–5). IBR approved for § 20.1010(a).

(viii) ICRP Publication 130 - ICRP, 2015. “Occupational Intakes of Radionuclides: Part 1.” ICRP Publication 130. Ann. ICRP 44(2). IBR approved for § 20.1010(a).

(ix) ICRP Publication 134 - ICRP, 2016. “Occupational Intakes of Radionuclides: Part 2.” ICRP Publication 134. Ann. ICRP 45(3/4), 1–352. IBR approved for § 20.1010(a).

(x) ICRP Publication 137 - ICRP, 2017. “Occupational Intakes of Radionuclides: Part 3.” ICRP Publication 137. Ann. ICRP 46(3/4). IBR approved for § 20.1010(a).

(xi) ICRP Publication 141 - ICRP, 2019. “Occupational Intakes of Radionuclides: Part 4.” ICRP Publication 141. Ann. ICRP 48(2/3). IBR approved for § 20.1010(a).

(xii) ICRP Publication 144 - ICRP, 2020. “Dose Coefficients for External Exposures to Environmental Sources.” ICRP Publication 144. Ann. ICRP 49(2). IBR approved for § 20.1010(a).

(xiii) ICRP Publication 151 - ICRP, 2022. “Occupational Intakes of Radionuclides: Part

5." ICRP Publication 151. Ann. ICRP 51(1–2). IBR approved for § 20.1010(a).

(b) ***Conditions.*** Per § 20.1010(a), unless otherwise approved by the NRC, alternative dosimetry methods must be consistent with one or more of the standards listed in paragraph (a), subject to the following conditions:

(1) ***American National Standards Institute/American Nuclear Society (ANSI/ANS)—***

(i) ANSI/ANS-6.1.1-2020 – No conditions.

(***2) International Commission on Radiological Protection (ICRP)—***

(i) ICRP Publication 56 – Only the following sections may be used as alternative dosimetry methods: Glossary, Section I Chapters 1-3, Section II Chapters 1-12, and Annexes A-B.

(ii) ICRP Publication 67 - Only the following sections may be used as alternative dosimetry methods: Glossary, Introduction, Computation of Age-Dependent Effective Dose Coefficients, Chapters 1-13, and Appendices A-C.

(iii) ICRP Publication 68 - Only the following sections may be used as alternative dosimetry methods: Glossary, Chapters 1-6 and 8, and Annexes A-F.

(iv) ICRP Publication 69 - Only the following sections may be used as alternative dosimetry methods: Glossary, Introduction, Computation of Age-Dependent Effective Dose Coefficients, and Chapters 1-5.

(v) ICRP Publication 71 - Only the following sections may be used as alternative dosimetry methods: Glossary, Chapters 1-5, and Annexes A-D.

(vi) ICRP Publication 72 - Only the following sections may be used as alternative dosimetry methods: Glossary, Chapters 1-5, and Annexes A-B.

(vii) ICRP Publication 116 - Only the following sections may be used as alternative dosimetry methods: Chapters 1–5, Annexes A–J, and Supplementary Material.

(viii) ICRP Publication 130 - Only the following sections may be used as alternative dosimetry methods: Glossary, Chapter 1, Chapter 3, Section 6.5, and Chapter 7.

(ix) ICRP Publication 134 - Only the following sections may be used as alternative dosimetry methods: Chapters 1–15.

(x) ICRP Publication 137 - Only the following sections may be used as alternative dosimetry methods: Chapters 1–15, Annex A.

(xi) ICRP Publication 141 - Only the following sections may be used as alternative dosimetry methods: Chapters 1–28.

(xii) ICRP Publication 144 - Only the following sections may be used as alternative dosimetry methods: Chapters 2–9, Annexes A–C, and Supplementary Material.

(xiii) ICRP Publication 151 - Only the following sections may be used as alternative dosimetry methods: Chapters 1–39, Annexes A–B.

PART 34—LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

39. The authority citation for part 34 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

§ 34.3 [Amended].

40. In § 34.3, the definition for “ALARA” is removed.

§ 34.42 [Amended].

41. In § 34.42, remove paragraphs (c) and (d).

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

42. The authority citation for part 35 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

43. In § 35.2, add in alphabetical order definitions for “Administration regimen” and “Caregiver”.

§ 35.2 Definitions.

* * * * *

Administration regimen means the course of administrations of a given radiopharmaceutical or brachytherapy source as intended by the authorized user.

* * * * *

Caregiver means an adult who provides the patient with support or comfort for non-commercial gains following administration of byproduct material.

* * * * *

44. Revise and republish § 35.75 to read as follows:

§ 35.75 Release of individuals containing byproduct material.

(a) A licensee shall develop, implement, and maintain a written procedure to authorize release in accordance with paragraphs (b) and (c) of this section.

(b) A licensee may authorize the release from its control of any individual who has been administered byproduct material if—

(1) the licensee has written consent from the released individual or, as necessary, the released individual’s parent or guardian, and, if applicable, the released individual’s caregiver; and in situations involving a caregiver, the released individual or, as necessary, the released individual’s parent or guardian, and the released individual’s caregiver have been instructed on the radiation risks to the caregiver and methods to manage exposure to the caregiver if the total effective dose equivalent to the caregiver is likely to exceed 5 mSv (0.5 rem) and is not likely to exceed 50 mSv (5 rem) per patient administration regimen.

(2) the total effective dose equivalent to any other individual who is not a caregiver from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) per patient administration regimen.[1]

(c) A licensee shall provide the released individual or, as necessary, the released individual's parent or guardian, with instructions, including written instructions, on actions recommended to reduce contamination and maintain doses to other individuals below the limits in paragraphs (b)(1) and (b)(2) of this section if the total effective dose equivalent to any other individual, including a caregiver, is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(d) A licensee shall maintain a record of the written procedure(s) used for authorizing the release of individuals containing byproduct material in accordance with § 35.2075(a).

[1] The current revision of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," describes methods for calculating doses to caregivers and other individuals.

45. Revise and republish § 35.2075 to read as follows:

§ 35.2075 Records of procedures used for release of individuals containing byproduct material.

(a) A licensee shall retain a copy of the procedure(s) required by § 35.75(a) for the duration of the license.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

46. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

47. Amend Appendix A to 10 CFR part 40:

a. In the Introduction, revise the first and fifth paragraphs;

b. In Section I. Technical Criteria, Criterion 6, paragraph (6), revise the undesignated second paragraph; and

c. In Section I. Technical Criteria, Criterion 8, revise the first paragraph.

The revisions read as follows:

Appendix A to Part 40 —Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content

Introduction. Every applicant for a license to possess and use source material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required by the provisions of § 40.31(h) to include in a license application proposed specifications relating to milling operations and the disposition of tailings or wastes resulting from such milling activities. This appendix establishes technical, financial, ownership, and long-term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located. As used in this appendix, the term “as low as is reasonably achievable” has the

same meaning as in 40 CFR part 192.

* * * * *

All site specific licensing decisions based on the criteria in this appendix or alternatives proposed by licensees or applicants will take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the Commission determines to be appropriate. In implementing this appendix, the Commission will consider “practicable” and “reasonably achievable” as equivalent terms. Decisions involving these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

* * * * *

I. Technical Criteria

* * * * *

Criterion 6 —

(6) * * *

Byproduct material containing concentrations of radionuclides other than radium in soil, and surface activity on remaining structures, must not result in a total effective dose equivalent (TEDE) exceeding the dose from cleanup of radium contaminated soil to the above standard (benchmark dose). If more than one residual radionuclide is present in the same 100-square-meter area, the sum of the ratios for each radionuclide of concentration present to the concentration limit will not exceed "1" (unity). A calculation of the potential peak annual TEDE within 1000 years to the average member of the critical group that would result from applying the radium standard (not including radon) on the site must be submitted for approval. The use of decommissioning plans with benchmark doses that exceed 100 mrem/yr requires the approval of the Commission

after consideration of the recommendation of the NRC staff. This requirement for dose criteria does not apply to sites that have decommissioning plans for soil and structures approved before June 11, 1999.

* * * * *

Criterion 8 —Milling operations must be conducted so that all airborne effluent releases are managed primarily by use of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are managed to the extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. During operations and prior to closure, radiation doses from radon emissions from surface impoundments of uranium or thorium byproduct materials must be managed to the extent reasonably achievable.

* * * * *

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

48. The authority citation for part 50 is revised to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note.

49. In § 50.34, revise paragraphs (a)(1)(ii)(D)(*1*) and (*2*), and paragraph (f)(2)(xv) to read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(1) * * *

(ii) * * *

(D) * * *

(*1*) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem[4] total effective dose equivalent (TEDE), or total effective dose (TED), as applicable.

(*2*) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE), or total effective dose (TED), as applicable.

* * * * *

* * * * *

(f) *** * ***

(2) *** * ***

(xv) Provide a capability for containment purging/venting designed to minimize the purging time in consideration of the occupational dose limits set forth in part 20 of this chapter. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions. (II.E.4.4)

* * * * *

[4] A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, in order to assure that such designs provide assurance of low risk of public exposure to radiation, in the event of such accidents.

*****

50. In § 50.34a, revise paragraphs (a), (d)(1), and (e)(1) to read as follows:

§ 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors.

(a) An application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including anticipated operational occurrences. In addition to the information required under paragraph (b) of this section, the application shall identify the design objectives, and the means to be employed, for adequate control of radioactive materials in effluents to unrestricted areas.[1] The guides set out in appendix I to this part provide acceptable design objectives; alternative design objectives approved by the NRC are also acceptable. The guides in appendix I are not to be construed as radiation protection standards.

(d) * * *

(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section, and the design objectives, and the means to be employed, for adequate control of radioactive materials in effluents to

unrestricted areas;[1] and

(e) * * *

(1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section, and the design objectives, and the means to be employed, for adequate control of radioactive materials in effluents to unrestricted areas;[1] and

* * * * *

[1] In the case of an application filed before [EFFECTIVE DATE OF FINAL RULE], the application may instead identify the design objectives, and the means to be employed, that are based on keeping levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable. The term "as low as is reasonably achievable" as used in this footnote means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest. The guides set out in Sections I through V of appendix I to this part provide acceptable design objectives for this approach.

51. Revise and republish § 50.36a to read as follows:

§ 50.36a Technical specifications on effluents from nuclear power reactors.

(a) To maintain adequate control of releases of radioactive materials to unrestricted areas during normal conditions, including anticipated operational occurrences, each license authorizing operation of a nuclear power reactor and each application for a design certification or a manufacturing license will include technical specifications that, in addition to requiring compliance with applicable provisions of § 20.1301 of this chapter, require that:

(1) Operating procedures developed pursuant to § 50.34a(c)(1) for the control of effluents be established and followed and that the equipment installed in radioactive waste systems, pursuant to § 50.34a(c)(1), be maintained and used. The licensee shall retain the operating procedures in effect as a record until the Commission terminates the

license and shall retain each superseded revision of the procedures for 3 years from the date it was superseded.

(2) The holder of either an operating license under this part or a combined license under part 52 after the Commission has made the finding under § 52.103(g) of this chapter for a nuclear power reactor using the technical specifications must develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the surveillance and monitoring program required by paragraph (a)(3) during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in § 50.71(c). The technical specifications required by paragraph (a) of this section shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in § 50.4. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(3) Each licensee subject to paragraph (a)(2) of this section must establish an appropriate surveillance and monitoring program to:

(i) Provide data on quantities of radioactive material released in liquid and gaseous effluents to assure that the provisions of paragraph (a) of this section are met;

(ii) Provide data on measurable levels of radiation and radioactive materials in the environment to evaluate the relationship between quantities of radioactive material released in effluents and resultant radiation doses to individuals from principal pathways of exposure; and

(iii) Identify changes in the use of unrestricted areas (e.g., for agricultural purposes) sufficient to evaluate the effectiveness of and enable modifications, if necessary, to monitoring programs for evaluating doses to individuals from principal pathways of exposure.

(b) In establishing and implementing the technical specifications described in paragraph (a) of this section, the licensee shall include limiting conditions for operation such that adequate opportunity is available for licensee action and NRC notification prior to exceeding applicable limits. The guides set out in appendix I to this part provide one acceptable approach for meeting the requirements of this paragraph; alternative approaches approved by the NRC are also acceptable.

(c) If the data collected by the surveillance and monitoring program described in paragraph (a)(3) of this section or by other monitoring programs show that the relationship between the quantities of radioactive material released in liquid and gaseous effluents and the dose to individuals in unrestricted areas is significantly different from that assumed in the calculations used to determine design objectives pursuant to § 50.34a, the Commission may modify the quantities in the technical specifications defining the limiting conditions in a license to operate a nuclear power reactor or a license whose holder has submitted a certification of permanent cessation of operations under § 50.82(a)(1).

52. In § 50.66, revise paragraph (b)(1)(iii) to read as follows.

§ 50.66 Requirements for thermal annealing of the reactor pressure vessel.

* * * * *

(b) * * *

(1) * * *

(iii) The methods, including heat source, instrumentation and procedures

proposed for performing the thermal annealing. This shall include any special precautions necessary to maintain occupational exposure within the limits set forth in part 20 of this chapter.

* * * * *

53. In Appendix I to part 50:

a. Revise the title of Appendix I;

b. In Section IV, revise paragraph C; and

c. Add Section VI.

The revisions and addition read as follows:

Appendix I to Part 50—Acceptable Design Objectives and Limiting Conditions for Operation to Maintain Adequate Control of Radioactive Material in Nuclear Power Reactor Effluents

* * * * *

SECTION IV

* * * * *

C. If the data collected by the surveillance and monitoring program described in paragraph B of Section III or by other monitoring programs show that the relationship between the quantities of radioactive material released in liquid and gaseous effluents and the dose to individuals in unrestricted areas is significantly different from that assumed in the calculations used to determine design objectives pursuant to Sections II and III, the Commission may modify the quantities in the technical specifications defining the limiting conditions in a license to operate a light-water-cooled nuclear power reactor or a license whose holder has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110.

* * * * *

Section VI. *Alternative acceptable design objectives and limiting conditions for operation*

to maintain adequate control of radioactive material in nuclear power reactor effluents.

This section provides an alternative acceptable to the NRC to the approach described in Sections I–V of this appendix for establishing technical specifications under § 50.36a to maintain adequate control of releases of radioactive materials to unrestricted areas during normal conditions, including anticipated operational occurrences.

A. The design objective for adequate control of radioactive material in effluents is that the calculated total quantity of all radioactive material above background to be released from each nuclear power reactor to the unrestricted area will not result in an estimated total effective dose equivalent, or total effective dose, as applicable, of more than 25 mrem per year.

B.

1. Licensees may use the methods described in Section III and associated guidance to demonstrate conformity with the design objective of Section VI.A. Alternatively, licensees may use the guides in Section VI.C to demonstrate conformity with the design objective of Section VI.A.

2. In demonstrating conformity with the design objective of Section VI.A, a licensee may use alternative dosimetry methods as described in § 20.1010.

3. In establishing technical specifications pursuant to § 50.36a, licensees can use administrative controls per § 50.36(c)(5) to describe general aspects of the program to maintain adequate control of releases of radioactive materials to unrestricted areas during normal conditions, including anticipated operational occurrence, and to describe implementation of the recordkeeping and reporting requirements of § 50.36a(a)(2). Additional details, including controls for specific equipment, applicability statements, actions, and surveillance requirements can be maintained in licensee-controlled documents whose configuration would be managed with an administrative control per § 50.36(c)(5).

C. The guides on technical specifications for limiting conditions for operation or administrative controls for nuclear power reactors set forth below may be used by an applicant for an operating license under this part or a design certification, manufacturing license or combined license under part 52 of this chapter, or by a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 of this chapter, as guidance in developing technical specifications pursuant to § 50.36a(a) to adequately control releases of radioactive materials in effluents to unrestricted areas.

1. If the quantity of radioactive material actually released in effluents to unrestricted areas from a nuclear power reactor during any calendar quarter is such that the resulting radiation exposure, calculated on the same basis as the respective design objective exposure, would exceed one-half the design objective in Section VI.A, the holder of an operating license or combined license shall:

(a) Make an investigation to identify the causes for such release rates;

(b) Define and initiate a program of corrective action; and

(c) Record these actions in the appropriate annual report that is required by § 50.36a(a)(2).

2. If the quantity of radioactive material actually released in effluents to unrestricted areas from a nuclear power reactor during any calendar quarter is such that the resulting radiation exposure, calculated on the same basis as the respective design objective exposure, would exceed the design objective in Section VI.A, the licensee shall complete the actions of paragraph VI.C.1 and submit the annual report that is required by § 50.36a(a)(2) to the Commission at the conclusion of the monitored year as specified in § 50.4. The licensee shall continue to submit annual reports to the Commission until the report after conformity with the design objective of Section VI.A is restored.

3. The surveillance and monitoring program required by § 50.36a(a)(3) shall include administrative controls that:

(a) Provide data and controls on the quantities of radioactive material released in liquid and gaseous effluents to assure that the design objective of Section VI.A is met;

(b) Provide data on measurable levels of radiation and radioactive materials in the environment to evaluate the relationship between quantities of radioactive material released in effluents and resultant radiation doses to individuals from principal pathways of exposure; and

(c) Identify changes in the use of unrestricted areas (e.g., for agricultural purposes) to permit modifications in monitoring programs for evaluating doses to individuals from principal pathways of exposure.

(d) Ensure proper use and maintenance of equipment used to monitor and control releases of radioactive materials to unrestricted areas during normal conditions, including anticipated operational occurrences.

4. If the data developed in the surveillance and monitoring program described in § 50.36a(a)(3) or from other monitoring programs show that the relationship between the quantities of radioactive material released in liquid and gaseous effluents and the dose to individuals in unrestricted areas is significantly different from that assumed in the calculations used to determine design objectives pursuant to Section VI.A, the Commission may modify the quantities in the technical specifications defining the limiting conditions in a license to operate a nuclear power reactor or a license whose holder has submitted a certification of permanent cessation of operations under § 50.82(a)(1).

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS

54. The authority citation for part 53 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 161,

181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Pub. L. 115-439, 132 Stat. 5571.

55. In § 53.210, revise paragraphs (a) and (b) and footnote 1 to read as follows:

§ 53.210 Safety criteria for design-basis accidents.

* * * * *

(a) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 millisieverts) total effective dose equivalent (TEDE), or total effective dose (TED), as applicable; and

(b) An individual located at any point on the outer boundary of the low-population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 millisieverts) TEDE, or TED, as applicable[1].

[1]The use of 25 rem is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

56. In § 53.530, revise paragraphs (a)(1) and (2) to read as follows:

§ 53.530 Population-related considerations.

* * * * *

(a) * * *

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 millisieverts) total effective dose equivalent, or total effective dose, as applicable.

(2) An individual located at any point on the outer boundary of the low-population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 millisieverts) total effective dose equivalent, or total effective dose, as applicable.

* * * * *

57. In § 53.850, revise paragraphs (a) and (b)(2) to read as follows:

§ 53.850 Radiation protection.

(a) Each holder of an OL or COL under this part must develop, implement, and maintain a Radiation Protection Program for operations that is commensurate with the scope and extent of licensed activities under this part and includes measures for controlling and monitoring radioactive plant effluents and controlling and monitoring the dose to individuals working with radioactive materials in accordance with 10 CFR part 20 of this chapter.

(b) * * *

(2) Contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the report, or reports, required by § 53.1645.

* * * * *

58. In § 53.1645, revise paragraph (a) and remove and reserve paragraph (b) to

read as follows:

§ 53.1645 Reports of radiation exposure to members of the public.

(a) Each holder of an OL, and each holder of a COL after the Commission has made the finding under § 53.1452(g), must develop and maintain a report, or reports, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and the results of the control and monitoring program required by §§ 53.850(a) and 53.850(b) during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records as specified in § 53.1620. The program required by §§ 53.850(a) and 53.850(b) shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in § 53.040. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(b) [Reserved]

PART 61—LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

59. The authority citation for part 61 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 65, 81, 161, 181,182, 183, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2231, 2232,2233, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 206, 211 (42 U.S.C.5841, 5846, 5851); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec.2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

§ 61.41 [Amended].

60. In § 61.41 the last sentence is removed.

§ 61.43 [Amended].

61. In § 61.43, the last sentence is removed.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

62. The authority citation for part 71 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 180 (42 U.S.C. 10175); 44 U.S.C. 3504 note.

Section 71.97 also issued under Sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

63. In § 71.87, revise paragraph (i) to read as follows:

§ 71.87 Routine determinations.

* * * * *

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is within the limits specified in DOT regulations in 49 CFR 173.443;

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

64. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

§ 72.3 [Amended]

65. In § 72.3, the definition for “As low as is reasonably achievable (ALARA)” is removed.

66. In § 72.24, revise paragraph (e) and paragraph (l) introductory text to read as follows:

§ 72.24 Contents of application: Technical information

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(e) The means for maintaining occupational radiation exposures within the limits given in part 20 of this chapter.

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(l) A description of the equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal operations and expected operational occurrences. The description must identify the design objectives and the means to be used for keeping levels of radioactive material in effluents to the environment within the exposure criteria stated in § 72.104. The description must include:

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67. In § 72.44, revise paragraph (d) introductory text and paragraph (d)(3) to read as follows:

§ 72.44 License conditions.

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(d) Each license authorizing the receipt, handling, and storage of spent fuel, high-level radioactive waste, and/or reactor-related GTCC waste under this part must include technical specifications that, in addition to stating the limits on the release of radioactive

materials for compliance with limits of part 20 of this chapter, require:

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(3) An annual report, or reports, be developed and maintained specifying the quantity of each of the principal radionuclides released to the environment in liquid and in gaseous effluents during the previous 12 months. The time between the development of the reports must be no longer than 12 months. The report, or reports, must include any information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases, or to independently verify results. The report, or reports, must be maintained as records until termination of the license. The technical specifications required by paragraph (d) of this section shall include requirements for when such a report, or reports, must be submitted to the Commission as specified in § 72.4. On the basis of these reports and any additional information that the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

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68. In § 72.104, revise paragraphs (b) and (c) and add (d) to read as follows:

§ 72.104 Criteria for radioactive materials in effluents and direct radiation from an ISFSI or MRS.

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(b) Operational restrictions must be established to meet direct radiation levels associated with ISFSI or MRS operations.

(c) Operational restrictions must be established for radioactive materials in effluents and direct radiation levels associated with ISFSI or MRS operations to meet the criteria given in paragraph (a) of this section.

(d) Licensees may use alternative dosimetry methods, per § 20.1010 of this chapter, to demonstrate compliance with criteria that are equivalent to the criteria given in paragraph (a) of this section. In these cases, the applicable criterion is 0.25 mSv (25 mrem) total effective dose equivalent, or total effective dose, as applicable.

69. In § 72.126, revise paragraph (d) to read as follows:

§ 72.126 Criteria for radiological protection.

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(d) *Effluent control.* The ISFSI or MRS must be designed to provide means for managing the release of radioactive materials in effluents during normal operations and controlling the release of radioactive materials under accident conditions. Analyses must be made to show that releases to the general environment during normal operations and anticipated occurrences will be within the exposure criteria given in § 72.104. Analyses of design basis accidents must be made to show that releases to the general environment will be within the exposure criteria given in § 72.106. Systems designed to monitor the release of radioactive materials must have means for calibration and testing their operability.

Dated: <Month XX, 20XX>.

For the Nuclear Regulatory Commission.

Carrie M. Safford,

Secretary of the Commission.