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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 190

[EPA-HQ-OAR-2013-0689; FRL-9902-20-OAR]

RIN 2060-AR12

### Environmental Radiation Protection Standards for Nuclear Power Operations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Advance Notice of Proposed Rulemaking.

**SUMMARY:** This Advance Notice of Proposed Rulemaking (ANPR) requests public comment and information on potential approaches to updating the Environmental Protection Agency's "Environmental Radiation Protection Standards for Nuclear Power Operations" (40 CFR part 190). These standards, originally issued in 1977, limit radiation releases and doses to the public from normal operation of nuclear power plants and other uranium fuel cycle facilities—that is, facilities involved in the milling, conversion, fabrication, use and reprocessing of uranium fuel for generating commercial electrical power. These standards were the earliest radiation rules developed by EPA and are based on nuclear power technology and the understanding of radiation biology current at that time. The Nuclear Regulatory Commission (NRC) is responsible for implementing and enforcing these standards.

**DATES:** Comments must be received on or before June 4, 2014.

**Additional Public Input.** In addition to this ANPR, the Agency anticipates providing additional opportunities for public input. Please see the Web site for more information at: [www.epa.gov/radiation/laws/190](http://www.epa.gov/radiation/laws/190).

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2013-0689, by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- Email: [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov).
- Fax: (202) 566-9744.
- Mail: U.S. Postal Service, send comments to: EPA Docket Center,

Environmental Radiation Protection Standards for Nuclear Power Operations—Advance Notice of Proposed Rulemaking Docket, Docket ID No. EPA-HQ-OAR-2013-0689, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.

- *Hand Delivery:* In person or by courier, deliver comments to: EPA Docket Center, Environmental Radiation Protection Standards for Nuclear Power Operations—Advance Notice of Proposed Rulemaking Docket, Docket ID No. EPA-HQ-OAR-2013-0689, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of two copies.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-OAR-2013-0689. The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or email. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov) your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm).

**Docket:** All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index,

some information is not publicly available, e.g., CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Docket Center is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** Brian Littleton, EPA Office of Radiation and Indoor Air, (202) 343-9216, [littleton.brian@epa.gov](mailto:littleton.brian@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### Fact Sheets

The Agency is making several fact sheets available to assist the public in understanding the issues related to the effort to update this rule. These fact sheets are as follows:

1. ANPR Fact Sheet
2. Radiation Regulations Fact Sheet
3. Uranium Fuel Cycle Fact Sheet

These fact sheets are available on the Agency's Web site associated with this effort at: [www.epa.gov/radiation/laws/190](http://www.epa.gov/radiation/laws/190).

#### Glossary of Terms

What are the important radiation-related concepts and terms we use in this ANPR? Radiation-related terms used in this ANPR are defined below.

**Absorbed dose**—The amount of energy absorbed by an object or person per unit mass. This reflects the amount of energy that ionizing radiation sources deposit in materials through which they pass.

**Advanced Boiling Water Reactor (ABWR)**—New design of boiling water nuclear reactor which uses steam and high-pressure water to transfer energy to turbines. The NRC has detailed criteria for meeting this design in its design certification rule published in the **Federal Register** on May 12, 1997 (62 FR 25800).

**Advanced Passive Reactor 1000 (AP1000)**—New design of pressurized water nuclear reactor with passive safety features incorporated. It uses high-pressure water to transfer energy to a second low-pressure water loop. This secondary water is converted to steam which then drives the turbines. The NRC has detailed criteria for meeting

this design in its design certification rule published in the **Federal Register** on January 27, 2006 (71 FR 4464).

**Advanced Pressurized Water Reactor (APWR)**—New design of pressurized water nuclear reactor which uses high-pressure water to transfer energy to a second low-pressure water loop. This secondary water is converted to steam, which then drives the turbines. The NRC has received the U.S. APWR design certification application and is reviewing the application for compliance with NRC's regulations. The NRC has not yet certified the design under its regulations at 10 CFR part 52. However, if the NRC determines that the U.S. APWR design meets all applicable regulations, it will proceed to certify the design through the NRC's rulemaking process.

**Blue Ribbon Commission (BRC)**—The President's Blue Ribbon Commission on America's Nuclear Future was established as directed by the President's Memorandum for the Secretary of Energy dated January 29, 2010. The purpose of the 15-member BRC was to conduct a comprehensive review of policies for managing the back end of the nuclear fuel cycle and recommend a new plan.

**Boiling Water Reactor (BWR)**—A type of light-water nuclear reactor design which uses steam and high pressure water to transfer energy to turbines.

**Committed equivalent dose**—The equivalent dose (see definition below) to a tissue or organ that will be received for a specified period of time following intake of radioactive material. The committed dose allows an accounting of the total dose from radioactive materials taken into (and held in) the body, for which the dose will be spread out in time, being gradually delivered as the radionuclide decays.

**Committed effective dose (CED)**—The effective dose received over a period of time by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides. CED is expressed in units of sievert (SI units) or rem.

**Collective dose**—The sum of individual radiation doses to a specified group or population.

**Curie**—A unit of radioactivity, corresponding to  $3.7 \times 10^{10}$  disintegrations per second.

**Deterministic effects**—A health effect that has a clinical threshold (i.e., exposures below the threshold do not result in the effect of concern), beyond which the severity increases with the dose. Deterministic effects generally result from the receipt of a relatively high dose over a short time period.

**Radiation-induced cataract formation**

(clouding of the lens of the eye) is an example of a deterministic effect. These are also termed "non-stochastic" effects.

**Dose, or radiation dose**—A general term for absorbed dose, equivalent dose, effective dose, committed effective dose, committed equivalent dose or total effective dose as defined in this document. A measure of the energy deposited in tissue by ionizing radiation.

**Dosimetry**—The method used to calculate dose or other related measures of the impacts of exposure to radiation, taking into account the type of radiation and the duration and mode of exposure.

**Economic Simplified Boiling Water Reactor (ESBWR)**—New design of boiling water nuclear reactor which uses high-pressure steam to transfer energy to turbines. It takes advantage of natural circulation for normal operation and has passive safety features.

**Effective dose (E)**—This quantity, previously called the effective dose equivalent (EDE), is the weighted sum of the equivalent doses to individual organs of the body. The dose to each tissue or organ is weighted according to the risk that dose represents. These organ doses are then added together, and that total is the effective dose. The relevant units are rem or sieverts (SI units).

**Equivalent dose**—The product of absorbed dose (grays or rads), averaged over a tissue or organ, multiplied by a radiation weighting factor. The radiation weighting factor relates to the degree to which a type of ionizing radiation will produce biological damage. It is used because some types of radiation, such as alpha particles, are more biologically damaging to live tissue than other types of radiation when the absorbed dose from both is equal. Equivalent dose expresses, on a common scale for all ionizing radiation, the biological damage to the exposed tissue. It is expressed numerically in rems (traditional units) or sieverts (SI units). This quantity was also known as the "dose equivalent" until the change in terminology was adopted by the International Commission on Radiological Protection (ICRP).

**Evolutionary Power Reactor (EPR)**—New design of pressurized water nuclear reactor which uses high-pressure water to transfer energy to a second low-pressure water loop. This secondary water is converted to high-pressure steam which then drives the turbines.

**External dose**—That portion of the dose equivalent received from radiation sources outside the body.

**High-level radioactive waste**—The highly radioactive material resulting

from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and other highly radioactive material that the NRC, consistent with existing law, determines by rule requires permanent isolation.

**Internal dose**—That portion of the dose equivalent received from radioactive material taken into the body.

**International Commission on Radiological Protection (ICRP)**—The independent, international advisory body that develops the international system of radiological protection as a common basis for standards, legislation, guidelines, programs and practices. Recommendations of the ICRP are not legally binding but are typically given strong consideration by individual countries as representing the state-of-the-art in radiation protection.

**Maximum Contaminant Level (MCL)**—The highest level of a contaminant that EPA allows in drinking water.

**Mixed Oxide (MOX) Fuel**—Fuel fabricated from mixed uranium and plutonium oxide, which may be used in reactors.

**Non-stochastic effects**—Health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Non-stochastic effects generally result from the receipt of a relatively high dose over a short time period. Also called deterministic effects.

**Oxidation, REduction of enriched OXide (OREOX) process**—Fuel reprocessing technology which generates a mixed oxide fuel from spent nuclear fuel assemblies.

**Pressurized Water Reactor (PWR)**—A type of light-water reactor which uses high pressure water to transfer energy to a second low pressure water loop. This secondary water is converted to high-pressure steam which then drives the turbines.

**Radionuclide Release Limits**—In the context of this ANPR, the specific radionuclide release limits established under 40 CFR 190.10(b). These are the legally permissible maximum amounts of krypton-85, iodine-129, as well as plutonium-239 and other alpha emitters that can enter the environment from the processes of nuclear power operations in any given year, on an energy production basis.

**Radiation effects**—Health consequences from exposure to radiation. The effects may be either deterministic or stochastic.

**Radiation risk**—The probability or chance that a particular health effect will occur per unit dose of radiation.

**Rem**—The traditional unit of effective dose. It is the product of the tissue-weighted absorbed dose in rads and a radiation weighting factor,  $W_R$ , which accounts for the effectiveness of the radiation to cause biological damage; 1 rem = 0.01 Sv.

**Sievert (Sv)**—The sievert is the International System of Units (SI) term for the unit of effective dose and equivalent dose; 1 Sv = 1 joule/kilogram.

**Spent nuclear fuel reprocessing**—The initial separation of spent nuclear fuel into its constituent parts.

**Spent nuclear fuel reprocessing facility**—A building or complex of buildings where spent nuclear fuel reprocessing and other processes take place.

**Spent nuclear fuel storage**—The storage of spent nuclear fuel from nuclear fuel cycle and power operations. Storage can include the temporary holding of spent nuclear fuel after it has been removed from the nuclear reactor, up to and including any storage of spent nuclear fuel prior to final disposal. On-site storage at a nuclear power plant may include the spent nuclear fuel pools, where the spent nuclear fuel is held immediately after removal from the reactor for several years of initial cooling, as well as subsequent storage, for example, in large concrete and metal dry storage casks and vaults. This term would also apply to storage at any potential facility designed for the storage of spent nuclear fuel prior to its final disposition.

**Stochastic effect (of radiation)**—Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is assumed to be a function of dose without threshold as a conservative planning base.

**TED (total effective dose)**—The sum of the effective dose (for external exposures) and the committed effective dose (for internal exposures).

**Underground Source of Drinking Water (USDW)**—An aquifer or part of an aquifer which (a) supplies any public water system or contains a sufficient quantity of ground water to supply a public water system and currently supplies drinking water for human consumption or contains fewer than 10,000 milligrams/liter of Total Dissolved Solids (TDS); and (b) is not an exempted aquifer (see 40 CFR 144.3 for a complete definition).

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## I. Background

A. *What is the basis for the existing standards? How do the standards apply and what do they require?*

### 1. Statutory Authority

Section 161(b) of the Atomic Energy Act of 1954 (AEA) authorized the Atomic Energy Commission (AEC) to “establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property[.]” 42 U.S.C. 2201(b) (1958). In Reorganization Plan No. 3 of 1970, President Nixon transferred to EPA “[t]he functions of the Atomic Energy

Commission under the Atomic Energy Act of 1954, as amended, . . . to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material.” § 2(a)(6), 35 FR 15623, 15624 (Oct. 6, 1970) (“Reorganization Plan”). The Reorganization Plan defined “standards” to mean “limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.” *Id.* This transferred to EPA the portion of the AEC’s authority under AEA section 161(b) that “consist[ed] of establishing generally applicable environmental standards for the protection of the general environment from radioactive material.”

Reorganization Plan § 2(a)(6); *Quivira Mining v. U.S. Envt'l Prot. Agency*, 728 F.2d 477, 480 (10th Cir. 1984) (recognizing that the Reorganization Plan transferred to EPA certain AEA functions under AEA § 161(b)). Relying on this authority, EPA promulgated standards in 1977 to protect the public from exposure to radiation from the uranium fuel cycle at 40 CFR part 190, “Environmental Radiation Protection Standards for Nuclear Power Operations.”

### 2. History of the Standards

On May 10, 1974, the Agency published an advance notice of its intent to propose standards under this authority for the uranium fuel cycle and invited public participation in the formulation of this proposed rule (39 FR 16906). On May 29, 1975, EPA proposed regulations setting forth such standards (40 FR 23420). The Agency promulgated the environmental radiation standards in final form in 1977 (42 FR 2860, January 13, 1977). The standards specify the levels of public exposure and environmental releases below which normal operations of the uranium fuel cycle are determined to be environmentally acceptable. These standards have not been revised since their initial publication.

### 3. Scope and Content of the Standards

The existing standards apply to nuclear power operations, which are those operations defined to be associated with the normal production of electrical power for public use by any nuclear fuel cycle through utilization of nuclear energy. In 1977, the only nuclear fuel cycle in production within the U.S. was the uranium fuel cycle;

thus, EPA developed specific standards for this industry. The uranium fuel cycle is defined as the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these directly support the production of electrical power for public use utilizing nuclear energy, but excludes mining operations, operations at waste disposal sites, transportation of any radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and by-product materials from the cycle. (Commercial reprocessing has not occurred within the U.S. since the publication of the existing standards.) The Agency has developed some supporting information to help the public further understand the uranium fuel cycle which is located on the Agency's Web site for this rulemaking at [www.epa.gov/radiation/laws/190](http://www.epa.gov/radiation/laws/190). The existing standards do not address two other aspects of nuclear power production: The disposal of radioactive waste and the decommissioning of facilities.

The regulation contains two main provisions: A dose limit to members of the public, and a radionuclide release limit to the environment. The provision specified in 40 CFR 190.10(a) limits the annual dose to any member of the public from exposures to planned releases from uranium fuel cycle facilities to 25 millirem (mrem) to the whole body, 75 mrem to the thyroid, and 25 mrem to any other organ. Additionally, the provision specified in 40 CFR 190.10(b) limits the total quantity of radioactive material releases for the entire uranium fuel cycle, per gigawatt-year of electrical energy produced, to less than 50,000 curies of krypton-85, 5 millicuries of iodine-129 and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year.

#### 4. Technical Basis for the Standards

The document *Environmental Radiation Protection Requirements for Normal Operations of Activities in the Uranium Fuel Cycle: Final Environmental Statement* (FES) (EPA Publication no. 520/4-76-016, 1976) provided the basis for developing 40 CFR part 190. This document states that at that time there were three fuels available for commercial nuclear power: Uranium-235, uranium-233 and plutonium-239. The first of these

materials occurs naturally and the last two occur as products and/or by-products in uranium-fueled reactors (uranium-233 is the product of neutron irradiation of thorium-232). In the United States, the early development of technology for the nuclear generation of electric power focused around the light-water-cooled nuclear reactor (LWR), which utilizes uranium-235 fuel. For this reason, the standards considered only the use of enriched uranium-235 as fuel for the generation of electricity.

Additionally, the EPA projected that well over 300,000 megawatts (300 gigawatts) of nuclear electric generating capacity would exist within the next twenty years.<sup>1</sup> The part of the standards that pertain to the end of the fuel cycle relied on two assumptions: The availability of commercial nuclear reprocessing and the existence of a repository for final disposition for spent nuclear fuel and high-level radioactive wastes. The FES and supporting technical studies, which form the basis for the 40 CFR part 190 standards, include calculations of projected releases into the environment based on estimates of the growth of the nuclear industry. None of these assumptions has materialized.

#### B. Why is the Agency considering updating/revising the standards?

##### 1. What has changed and why could these changes be important?

The standards developed under 40 CFR part 190 were never intended to be static. The 1975 proposal (40 FR 23420, May 29, 1975) stated: "it is the intent of the Agency to maintain a continuing review of the appropriateness of these environmental radiation standards and to formally review them at least every five years and to revise them, if necessary, on the basis of information that develops in the interval." However, given the relatively limited change in the nuclear power industry in the intervening decades, we continued to believe that these standards remained protective of public health and the environment so we did not consider it necessary to update the standards. Nonetheless, we recognize that they do not reflect the most recent scientific information, and that this may be an opportune time to conduct a thorough review of their continued applicability. Therefore, the EPA is issuing this ANPR at this time for a number of reasons, including:

<sup>1</sup> The total current U.S. generating capacity is approximately 101 gigawatts for 2010 based on data provided by U.S. Energy Information Administration: [www.eia.gov/cneaf/nuclear/page/nuc\\_generation/gensum.html](http://www.eia.gov/cneaf/nuclear/page/nuc_generation/gensum.html).

- *Projected Growth of Nuclear Power.* Growing concern about greenhouse gas emissions from fossil fuels has led to renewed interest in nuclear power. Nuclear energy emits very low levels of greenhouse gases, and unlike solar and wind power, provides a proven source of electricity capable of supplying a base-load that is not subject to varying weather conditions. The nuclear industry anticipates a demand for construction of several new nuclear power plants in the next 10 years. Increased demand would likely result in the construction and start-up of any additional facilities to support the fuel cycle for LWRs. Other parts of the fuel cycle are experiencing growth as well. For example, new uranium enrichment facilities are coming on line, such as the facility in Eunice, New Mexico by Louisiana Enrichment Services (Urenco USA). The facility was licensed by the NRC in 2006, began operations in 2010, and is an indication of the industry's improved outlook. The licensing and operation of spent nuclear fuel reprocessing facilities are not expected in the near future.

- *Advances in Radiation Protection and Dosimetry Science.* National and international guidance on radiation protection have had three significant revisions since 40 CFR part 190 was issued. In the 1980s, the organ dose-based system used in 40 CFR part 190 was replaced with a system that integrated organ doses into a single expression of dose, which employed mortality risk-based weighting factors such that the dose term was a surrogate for risk (*International Commission on Radiological Protection (ICRP) Publications 26 and 30*). This new approach allowed the use of one dose limit for all radionuclides taken into the body, as well as for external exposures. Individual dose factors were established for all radionuclides and weighting factors for various organs were risk-based. Numerous regulations used this methodology, including NRC's 10 CFR part 20, and EPA's 40 CFR part 61 radionuclide emission standards. In addition, this methodology was used in EPA's internal and external dose factors in *Federal Guidance Report Nos. 11 and 12*. In the 1990s, ICRP improved the dosimetry models for ingestion and inhalation, expanded the number of organ-specific weighting factors and revised them to be based on new mortality and morbidity data. The risk factors in EPA *Federal Guidance Report No. 13* were based on this new dosimetry. In 2007, ICRP 103 was issued and the associated dosimetry is under development. In addition to improved

intake data and models, ICRP also addressed age- and gender-specific elements in the models. This information will be the basis for revising existing *Federal Guidance Reports*, which include radionuclide specific dose and risk factors.

- *Advances in Radiation Risk Science.* Advances in radiation risk science since 1977 have led to a better understanding of the health risks from ionizing radiation in general, as well as from specific radionuclides. Improved tools and methods for calculating radiation exposure have also become available. These advancements make more sophisticated radiological risk assessments possible. The Agency intends to review this standard to ensure its continued protectiveness in light of these advances. The Agency believes that the science used for the regulation is out of date and should be updated.

- *On-site Storage of Spent Nuclear Fuel.* The 1977 standards were based on the assumption that most spent nuclear fuel would be reprocessed following short-term storage on-site and that the U.S. would have a national repository for permanent disposal of high-level radioactive wastes and any remaining spent nuclear fuel in a time frame that would eliminate the need for longer-term storage. However, spent nuclear fuel currently is held at nuclear power plants in spent nuclear fuel storage casks or in storage pools as the U.S. determines a long-term disposal solution. Increased interest in nuclear power has also raised the prospect of commercial reprocessing of spent nuclear fuel. Nevertheless, near-term projections indicate that spent nuclear fuel could remain on site at the power plants during the operational life of existing nuclear power plants and into (or beyond) the decommissioning phase. The President's Blue Ribbon Commission on America's Nuclear Future has also identified this as an issue, especially for decommissioned facilities.

- *Extension of Nuclear Reactor Licenses.* Many of the nuclear reactors in the U.S. were built in the 1960s and 1970s. These reactors either are approaching their initial 40-year operational license limit, or they have exceeded this time period and continue to operate under license renewals. Regardless of the age of the reactor (or other facility), any U.S. reactor would still need to meet the EPA standards.

- *Ground Water.* Ground water contamination has been identified at a number of nuclear power plants and nuclear fuel cycle facilities. The existing standard contains release limits that

were intended to address the issue of long-lived radionuclides in the environment. However, the rule was developed under the assumption that air was the primary exposure pathway, and in contrast to more recent EPA radiation standards, it does not include a separate provision for protecting ground water outside facility boundaries that could be a current or future source of drinking water. The Agency is considering whether, and if so, how to develop a ground water provision.

## 2. Guiding Principles for Review of the Existing Standards

This review of the existing standards has two key principles. The first is that a thorough assessment of the potential impact on public health should be based on an up-to-date consensus of currently available scientific knowledge. The second is that careful consideration should be given to the cost and effectiveness of measures available to reduce or eliminate radioactive releases to the environment. In the development of the existing standards, the Agency found it necessary to "balance the health risks associated with any level of exposure against the costs of achieving that level" (39 FR 16906, May 10, 1974). The standard-setting method conducted in the current standards has been "best characterized as cost-effective health risk minimization" (*Final Environmental Statement*, 1976, Vol. 1, p. 28). As the Agency considers these principles, we are committed to ensuring that any revision is based on current science to the extent practicable and remains protective of public health and the environment while seeking alternative ways (methodologies), within the Agency's authorities, to limit public exposure. The Agency may revise several of the technical criteria used as a basis for the existing regulation or add new criteria to the regulation.

## C. What is the purpose of this ANPR and how will the Agency use the information?

This Advance Notice of Proposed Rulemaking is being published to inform stakeholders, including federal and state entities, the nuclear industry, the public and any interested groups, that the Agency is reviewing the existing standards to determine how the standards should be updated. As noted earlier, EPA believes the existing standards remain protective of public health and the environment; however, the Agency also believes that the changes mentioned above are sufficient to warrant a review of the standards and solicit public input on possible updates. EPA has identified six broad topics that

it believes capture the issues of most importance for a review of the existing standards. The Agency is requesting public comment on these specific topics; however, members of the public are welcome to comment on other aspects related to the nuclear fuel cycle that they believe EPA should consider.

If the Agency decides to revise the existing standards, then the Agency would follow the procedures outlined in the AEA and the Administrative Procedure Act (APA) and publish a proposed rule in the *Federal Register*. Comments received on the ANPR will inform the development of a proposed rule and be used by the Agency to provide a clearer understanding of science, technology and other concerns and perspectives of stakeholders. The Agency will not respond directly to comments submitted on this ANPR. However, the public would have the opportunity to submit written comments on any proposed rule that might be developed.

## D. How can the public comment on the ANPR and get additional information?

The Agency welcomes comments on this ANPR as it reviews the existing standards. EPA has set up a Web site for the public to access the most up-to-date information regarding our review of these standards. This site contains detailed information related to this rule and any potential revision, including: a copy of the existing standards, copies of the *Final Environmental Statements* and the *Supplemental Environmental Statement* on which the existing standards are based, as well as related fact sheets.

EPA plans to conduct public webinars to discuss specific issues on which the Agency is seeking comment. Dates, times and presentation materials for the webinars will be available on the Web site at: [www.epa.gov/radiation/laws/190](http://www.epa.gov/radiation/laws/190).

## II. Issues for Public Comment

### A. Issue 1—Consideration of a Risk Limit To Protect Individuals. Should the Agency express its limits for the purpose of this regulation in terms of radiation risk or radiation dose?

#### 1. Why is this issue important?

The purpose of the 40 CFR part 190 environmental standards is to protect human health and the environment. Although the current compliance metric for worldwide radiation standards is, and traditionally has been, either radiation dose or some measurable concentration or activity level, the Agency desires feedback to determine the feasibility of expressing its limits for

the purpose of this regulation in terms of radiation risk.

Conformance with regulatory public dose limits has traditionally been demonstrated through modeling calculations and subsequent personal, environmental or emissions monitoring. Compliance with a risk-based standard would be accomplished in a similar manner and the limits would be expressed as the maximum risk that could be allowed to the receptor from radiation exposures at any given facility under regulatory control.

### 2. What concepts are important to understanding this issue?

The primary concern from radiation exposure at the levels relevant for non-emergency situations is the increased risk of cancer. Two forms of radiation exposure, internal and external exposure, can occur depending upon the location of the source relative to the receptor. Internal exposures occur when a person inhales or ingests contaminated air, food, water or soil. External exposures occur because a person is near sources of radioactivity which are emitting penetrating radiation, such as x-rays, gamma rays, beta particles or neutrons. It should be noted that since the rule limits itself to the uranium fuel cycle, sources of radiation from machines, such as x-ray units and particle accelerators, are not covered by EPA standards. The term “radiation dose,” as used in dose standards, is a risk-weighted measure derived from the physical quantity of absorbed dose to an organ or tissue. As defined in this ANPR, “radiation risk” is the probability of an individual incurring a particular health effect per dose of radiation. Both dose and risk are commonly expressed over a lifetime or annualized depending on regulatory implementation.

### 3. What does 40 CFR part 190 say and what is basis of the existing standards?

The existing standards have two components limiting exposures to the public. The first is a dose limit to members of the public, while the second is a limit on the quantity released of certain radionuclides or forms of radioactivity into the environment. The provision specified in 40 CFR 190.10(a) limits the annual dose to any member of the public from exposures to planned releases from uranium fuel cycle facilities to 25 mrem to the whole body, 75 mrem to the thyroid and 25 mrem to any other organ. The provision specified in 40 CFR 190.10(b) limits the total quantity of radioactive material releases for the entire uranium fuel cycle, per gigawatt-year of electrical energy

produced, to less than 50,000 curies of krypton-85, 5 millicuries of iodine-129 and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year. Though views of risks have changed since 1977, the limits in 40 CFR 190.10(a) and (b) have as a basis a consideration of acceptable risk which served as a guide in developing the limits.

### 4. What Agency and national policies and approaches could be relevant?

EPA considers risk in establishing standards and requirements across programs and environmental media. Consistent with this practice, the Agency has stated radiation-specific standards for protection of individuals in terms of dose, based on the underlying risk level.

If the Agency should decide to retain a dose standard in 40 CFR part 190, that standard would be related to a level of health risk. In some cases, standards are expressed in terms of environmental flux (release rate) or concentration of radionuclides in the environment, but are also related to health impacts.

EPA has heard from some stakeholders that a standard expressed as a level of risk could be more understandable for those less familiar with radiation science, as it would more clearly state the health outcome that the Agency views as acceptable. EPA believes it would also assist commenters in evaluating the merits of a risk standard if the Agency referred to the reasoning employed by the National Research Council/National Academy of Sciences (the NAS committee) in its 1995 report, *Technical Bases for Yucca Mountain Standards*. The NAS committee recommended that EPA adopt a standard expressed as risk for two reasons. First, a risk standard is advantageous relative to a dose-based standard because it represents a societal judgment regarding health impacts and therefore “would not have to be revised in subsequent rulemakings if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today.” Second, a standard in the form of risk more readily enables the public to comprehend and compare the standard with human-health risks from other sources (*Technical Bases for Yucca Mountain Standards*, 1995, 64–65).<sup>2</sup>

<sup>2</sup> A different NAS committee expressed similar views in a 2002 report, *The Disposition Dilemma*, pp. 33–34.

### 5. How would a risk standard compare to a dose standard?

Planned or routine releases of radionuclides from nuclear fuel cycle facilities represent low-level ionizing radiation exposures to the public. As such, these non-emergency releases represent a potential increased risk of cancer to the public. Once an acceptable level of protection is identified, it may be translated to a release rate, as radionuclide concentrations in specific media, or another measurable unit, which can then serve as a regulatory limit expressed over time. Alternatively, site-specific modeling may be employed, based on measured releases, to calculate a dose or risk for comparison to the regulatory standard. This general approach to implementation would be used whether the standard is expressed in terms of risk or dose. As noted earlier, the compliance metric for radiation standards has more traditionally been either radiation dose or some measurable concentration or activity level.

Both calculated doses and risks from radiation exposure differ depending on the specific radionuclides involved, as well as the pathways of exposure. The same activity level received by an exposed individual from different radionuclides or through different pathways leads to a different dose and carries different risks. If someone is exposed to multiple radionuclides, the risk of adverse health effects is determined by summing the risks from each radionuclide involved in the exposure. The primary technical difference between a risk standard and a dose standard is that the relationship between risk and dose has varied over time.<sup>3</sup> Should this trend continue, there is the potential for a dose standard to diverge over time from its original underlying risk level. In contrast, a risk standard represents a constant level of risk, regardless of the type of facility, mix of radionuclides or changes in the underlying science involved in estimating the risk. Because it directly states the expectation for health outcome rather than relying on an overall correlation, it would typically not require an update, unless there are changes in what society deems an acceptable risk. If the standard were implemented by rule using measurable quantities such as effluent limits, however, these criteria would need to be updated, as they would be if a dose

<sup>3</sup> For example, the estimated risk of fatal cancer per rem of exposure increased in each of our three rulemakings for high-level radioactive waste (1985, 1993, 2001).

standard changes. We are interested in stakeholder views on how this updating process might differ for a risk or dose standard.

Although our experience is that the risk per unit dose has generally increased over the years, the possibility also exists that further research may show that cancer risks are overestimated for a given dose or for certain radionuclides or exposure pathways. Another aspect to consider when assessing whether a risk standard would be appropriate is whether cancer morbidity (incidence) or cancer mortality (fatality) should be used as the basis for establishing any risk standard. While EPA often relies upon morbidity information for chemical carcinogens, the Agency has used mortality data as the basis of both its standards for disposal of transuranic and high-level radioactive wastes (40 CFR part 191) and the Yucca Mountain standards (40 CFR part 197). One factor to consider is that there appears to be increasing divergence between morbidity and mortality; in other words, estimates of cancer incidence from exposure to radiation continue to increase, but cancer fatality has grown at a slower rate or been reduced (*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*, 2011). As a result, the Agency will take comment on whether morbidity data or mortality data, or a combination, would be more appropriate for the establishment of a potential risk standard.

Although a risk standard, like a dose standard, would generally be implemented through modeling and the derivation of measurable quantities, the Agency is also aware that there may be some challenges specific to a risk standard, especially given that the regulatory system is based on dose, which is far more familiar to the radiation protection community and industry practice. If a standard were developed in the form of a risk level that was not to be exceeded, then any meaningful discussion on implementation would need to address how the risk would be translated into measurable quantities such as an effluent release rate into the environment, a concentration in environmental media, an intake by an individual or external radiation exposure at specific locations or to specific persons. As is the case with the current dose standard, proof of compliance would most likely rely heavily on the use of modeling results coupled with effluent data. Any accepted modeling use would need to be either detailed within the standard, or detailed by the implementing federal

agency, possibly through development of subsequent regulations.

As discussed earlier, the Agency recognizes that different radionuclides contribute to potential exposures. EPA further recognizes that different radionuclides are predominant at the different types of facilities within the nuclear fuel cycle. If the Agency were to move toward a risk standard, the Agency would conduct an analysis of the dose-risk relationship at the different types of facilities. What issues would the Agency need to consider with the implementation of a risk standard at the different facilities? For example, would the radionuclides of most concern for a given fuel cycle facility have different risk implications for different fuel cycle facilities? Could NRC implement a risk standard by establishing a corresponding dose limit that it determines would keep risks under the risk standard?

While the Agency has not determined whether the technical merits or costs associated with developing a risk standard warrant a change from the traditional dose limits, the Agency believes it is reasonable to take comment at this time on how a potential risk limit may be implemented. Such a discussion could also inform the consideration of costs of implementing a risk standard.

EPA also notes that both national and international radiation protection guidelines developed by bodies of non-governmental radiation experts, such as the ICRP and the National Council on Radiation Protection and Measurements (NCRP), generally recommend that radiation standards be established in terms of dose. National and international radiation standards, including the individual protection requirements in 40 CFR part 191, “Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Waste”, are established almost solely in terms of dose or concentration, not risk. Therefore, a risk standard would not allow a convenient comparison with the numerous existing dose guidelines and standards, nor with other sources of radiation exposure, but it would more readily allow comparisons to other EPA risk management decisions for chemicals.

Lastly, it is important to note the potential costs that could be associated with moving from a dose standard to a risk standard. At the time of publication of this ANPR, the Agency has no information regarding potential costs to the regulated community. The Agency is

seeking any data that are available on these potential costs.

## 6. Questions for Public Comment

As the Agency considers the issue of establishing a standard expressed in terms of risk, we believe it to be appropriate to better understand the merits of this approach. The industry currently uses a dose limit, and the Agency is seeking information on how the industry would be affected by this change.

Consequently, the Agency is seeking input on the following questions:

a. *Should the Agency express its limit for the purpose of this regulation in terms of radiation risk or radiation dose?*

b. *Should the Agency base any risk standard on cancer morbidity or cancer mortality? What would be the advantages or disadvantages of each?*

c. *How might implementation of a risk limit be carried out? How might a risk standard affect other federal regulations and guidance?*

B. Issue 2—*Updated Dose Methodology (Dosimetry). How should the Agency update the radiation dosimetry methodology incorporated in the standard?*

### 1. Why is this issue important?

The dosimetry used for the existing standards is outdated. Since the development of the existing dose standard, the methodology to calculate radiation exposure has changed with scientific progress. The existing standard has separate limits for exposure of the whole body and exposure of specific organs. More recent dosimetry accounts for both types of exposures in a single numerical value that provides more consistency and allows easier comparison of radiation exposures, regardless of whether they are internal or external, or whether they are likely to affect single or multiple organs. Newer dosimetry approaches also reflect a better understanding of the different sensitivity of various organs and allow more sophisticated calculations of the impacts to individuals and even to specialized groups (i.e., children, sensitive subpopulations).

### 2. What does the existing standard say? What is the technical basis?

The standard in 40 CFR 190.10(a) states: “The annual dose equivalent [must] not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as the result of exposures to planned discharges of

radioactive materials, radon and its daughters excepted, to the general environment from uranium fuel cycle operations and to radiation from these operations.” These limits were based on the *Federal Radiation Protection Guidance* in existence at that time (26 FR 4402, May 18, 1960 and 26 FR 9057, September 26, 1961).

The federal guidance documents, in turn, were based on recommendations of the ICRP, which provides expert guidance on dose limits in view of the current understanding of dose-response relationships for exposure to ionizing radiation. Many international standards and national regulations addressing radiological protection are based on or take into account the ICRP’s recommendations. The guidance in effect during the development of the proposed<sup>4</sup> standards—ICRP Publication 2 (1959)—recommended dose limits aimed at avoiding deterministic effects and limiting stochastic effects, including leukemia and other cancers, as well as genetic effects. The dose limitation system at that time was based on the concept of the critical organ, defined as the organ or tissue most susceptible to damage from radiation. Separate dose limits were set for different groups of tissues, taking into account the potential for different types of radiation to cause greater damage depending on the mode of exposure. For example, alpha radiation poses less risk for external—or whole body—exposure because it is easily shielded even by the skin, but can cause greater damage to critical organs than other types of radiation when inhaled or ingested. These concepts, underlying the ICRP recommendations at the time, served as the basis of the existing dose limits to members of the public in 40 CFR part 190.

#### 3. What has changed and how are those changes important?

Since the publication of the existing regulation, advancements have been made in understanding radiation dosimetry. The ICRP updated its recommendations to reflect a better understanding of the different sensitivity of various organs and of the risks from different types of radiation. Of primary importance is that the critical organ concept was abandoned in favor of a new concept referred to as the effective dose equivalent (ICRP

<sup>4</sup> In the interim between publication of the proposed rule and publication of the final 40 CFR part 190 standards, ICRP 26 was finalized (adopted Jan 17, 1977). However sufficient time was not available to incorporate the ICRP 26 findings, and the Agency went forth with finalization of the proposed rule which was based on ICRP 2.

Publication 26, 1977). This new concept, later renamed effective dose (ICRP Publication 60, 1991), provides a single dose indicator that accommodates different types of radiation as well as different modes of exposure. The use of a unified dose facilitates understanding and comparison of the radiation exposures, regardless of whether they are internal or external, or whether they are likely to affect single or multiple organs. Further studies since the 1977 rule have also reinforced that some populations, such as pregnant women and children, are more sensitive to radiation and have allowed more specific calculations of risks to such groups. Such information is not reflected in the dose limits—or their form—in the existing uranium fuel cycle standards, which are based on the older “critical organ” system. Beyond the fact that the existing standards do not reflect the most recent scientific understanding, the use of an outmoded system also poses some compliance challenges. The models and methods to predict the dispersion of radionuclides, the modes of exposure, and the movement of radionuclides through the body (biokinetics) are more advanced today than in the past. However, the most sophisticated models are tailored to work with the more recent dosimetry systems and are not always compatible to assess compliance with limits expressed in the older systems. At the same time, the older models are less and less supported. This means that compliance assessments for the existing dose limit cannot take advantage of the best implementation tools. Thus, for reasons both scientific and practical, we believe it is worthwhile to consider how to update the dose methodology if the rule is revised.

#### 4. What policies and approaches are relevant?

As noted above, EPA’s dose limits take into account recommendations of the ICRP, which has updated its guidance documents several times since 40 CFR part 190 was issued. ICRP Publication 26 (1977) abandoned the critical organ concept of ICRP Publication 2 in favor of a new concept referred to as the effective dose equivalent (now called effective dose). The effective dose is a weighted sum of tissue doses intended to represent the same cancer risk from a non-uniform irradiation of the body as that from uniform whole body irradiation.<sup>5</sup> The

<sup>5</sup> In actuality, the weighting factors used to calculate effective dose equivalent are not sufficiently precise to equate risks for a given dose. The “true” risk is best calculated using

effective dose concept has been used in all subsequent ICRP publications to date.

The ICRP guidance was updated beyond ICRP 26 and expanded with ICRP Publication 60 (1991), based on additional information on the sensitivity of different tissues and organs in the body. ICRP 60 also made it possible to develop age- and gender-specific dose estimates. ICRP 60 has been widely implemented worldwide and serves as the basis for EPA radiation dose standards, notably the amended Yucca Mountain standards issued in 2008.

The Agency has explained its adoption of the effective dose concept in previous rulemakings. In the Agency’s 1989 Clean Air Act (CAA) rulemaking establishing National Emissions Standards for Hazardous Air Pollutants (NESHAPs) in 40 CFR part 61, Subpart I,<sup>6</sup> EPA said the following about effective dose equivalent (54 FR 51662, December 15, 1989):

Since 1985, when EPA proposed dose standards regulating NRC licensees and DOE facilities, a different methodology for calculating dose has come into widespread use, the effective dose equivalent (EDE). In 1987, EPA, in recommending to the President new guidance for workers occupationally exposed to radiation, accepted this methodology for the regulation of risks from radiation. This method, which was originally developed by the International Commission on Radiological Protection, will be used by EPA in all the dose standards promulgated in this ANPR. In the past, EPA dose standards were specified in terms of limits for specific organ doses and the ‘whole body dose’, a methodology which is no longer consistent with current practices of radiation protection.

The EDE is simple, is more closely related to risk, and is recommended by the leading national and international advisory bodies. By changing to this new methodology, EPA will be converting to the commonly accepted international method for calculating dose. This will make it easier for the regulated community to understand and comply with our standards.

The EDE is the weighted sum of the doses to individual organs of the body. The dose to each organ is weighted according to the risk that dose represents. These organ doses are then added together, and that total is the effective dose equivalent. In this manner, the risk from different sources of radiation can be controlled by a single standard.

radionuclide-specific, pathway-specific analyses and absorbed dose to an organ or whole body.

<sup>6</sup> Subpart I established standards for air emissions from NRC licensees, including uranium fuel cycle facilities, and non-DOE federal facilities not licensed by NRC. Subpart I was later rescinded based on the Administrator’s conclusion that NRC’s regulatory implementation protected public health with “an ample margin of safety” (60 FR 46206, September 5, 1995, and 61 FR 68972, December 30, 1996). Subpart I established standards for the air pathway of 10 mrem/year EDE, with no more than 3 mrem/year EDE from radioiodine.

This rulemaking (54 FR 51662) also noted that the EPA Science Advisory Board (SAB) commented that “EPA should use the effective dose equivalent concept for regulations protecting people from exposure to radiation.”

The latest update, in ICRP Publication 103 (2007), provided updated radiation protection guidance, including new tissue weighting (i.e., sensitivity) factors, but left the primary radiation protection guidance from 1991 virtually unchanged. ICRP 103 is the most recent guidance but, as discussed in more detail below, has not been applied in EPA regulations to date.

Other EPA policies are also relevant because, while the Agency takes into account ICRP guidance, regulatory limits must reflect additional factors. The ICRP recommended—in both Publication 60 and Publication 103—that public exposures be limited to 100 mrem (0.001 Sv) per year. However, this applies in principle to *all* man-made sources of radiation. In setting regulatory limits, we allow only a fraction of 100 mrem from a single source, such as a uranium fuel cycle facility. As discussed further in section II.A of this ANPR (“Consideration of a Risk Limit to Protect Individuals”), the dose limits used in our radiation regulations are based on an assessment of the associated risks. In the past, based on ICRP 26, EPA radiation policies and regulations have used 15 mrem/year as a dose limit that aligns with the Agency’s goals and corresponds to a limit of 25 mrem to the whole body and 75 mrem to any organ under the obsolete dose methodology for certain regulatory applications.<sup>7</sup> The corresponding dose under ICRP 103 has not been established. EPA is reviewing the implications of ICRP 103 for our revised dose and risk estimates. EPA will address the issue in a rulemaking if one is pursued.

It should be noted that the Agency does not have established policies or guidance on the application of age- and gender-specific dose calculations to determine compliance with a dose standard.<sup>8</sup> However, we are considering the application of age- and gender-specific dose calculations to determine compliance with the dose standard. Whether expressed in terms of risk or

dose, the standard must identify the person(s) against whom compliance will be assessed. The standards at 40 CFR part 190 currently specify that the dose standard applies to “any member of the public.” We have several other “any member of the public” standards that specify the use of ICRP 26 dosimetry and an associated concept, the “reference man.” Concerns have been raised that the “reference man” concept, combined with the fact that neither the ICRP 26 dosimetry nor the ICRP 2 methodology can provide age- and gender-specific calculations, does not assure that children or other vulnerable population segments are protected or adequately considered. The models beginning with ICRP 60 are able to address different age and gender cohorts, which allows the differing impact of radiation exposures to be evaluated. More specifically, ICRP Publication 89 (2002) provides anatomical and physiological data for males and females at ages newborn, 1 year, 5 years, 10 years, 15 years and adult that allow for age- and gender-specific estimates of dose to be calculated for these reference individuals. We note that, while the current standard is presented as an annual dose, it is established at a level that provides protection for an individual over a lifetime (i.e., at all ages). Nevertheless, we are examining the issue to confirm the protectiveness of our standards as written for all segments of the population.

Specifically, we are modifying the computer model CAP-88 PC, which is used to determine compliance with Clean Air Act radionuclide emission standards, to evaluate the relationship between radionuclide intake and dose for different age groups. This technical study will inform our review of our radiation protection policies, and we will make our findings available to the public. We anticipate that this question will be addressed broadly within the Agency to identify the most appropriate approach to resolving the issue as a whole, rather than for each individual rule. However, comments on the use of reference man or the appropriateness of specifying age- and gender-specific dose calculations are welcome. Such comments will be considered both in the context of this rule and as part of the overall Agency discussion on the topic.

5. What aspects of this issue are most important and what options might be considered to address this issue in any revised standards?

The Agency intends to review this portion of the regulation to ensure its continued protectiveness in light of

these technological advances. We acknowledge that the dose methodology on which the existing standard is based is now outmoded, and compliance with the existing standard poses some implementation challenges. These challenges are proving compliance with an organ-specific dose limit and with the current suite of compliance models using an effective dose methodology. As an example, most health physicists conducting compliance at nuclear power plant facilities are trained in the calculation and use of effective dose. Requiring compliance with an organ-specific dose necessitates the use of a different calculating technique, and potentially requires additional training. If the rule is revised, there would be little justification for retaining outdated science as the basis for dose limits. Therefore, the primary question is how the Agency would reflect more recent dose methodology. There are arguments to be made for using either ICRP 60 or ICRP 103, or for providing flexibility without specifying the ICRP basis.

As noted earlier, there is considerable experience worldwide in implementing the recommendations of ICRP 60. The EPA has issued guidance documents to allow detailed dose calculations for specific exposure situations, such as would be needed to determine compliance at a nuclear fuel cycle facility. A basis for calculating risks to more sensitive populations has also been developed, though (as noted earlier) there is not clear guidance on how, if at all, such information should be used in regulations.

The nuclear industry is familiar with the guidance and has experience in using compliance and assessment tools that are compatible with the ICRP 60 risk basis. Relying on ICRP 60 as the basis for a revised rule would eliminate any reference to an outdated individual organ calculation. The methodology is biologically and physically robust in its approach and has been properly peer-reviewed, implemented and supported by the publication of important federal guidance. This approach would provide a well-established methodology and compliance tools using science that is considerably more advanced than that used currently in 40 CFR part 190—but not the absolute most recent science.

Using the most recent science—which, in principle, is the preferred approach—would imply that ICRP 103 should be adopted as the basis for any revised rule. Unfortunately, ICRP 103 has not been widely utilized because the ICRP has yet to provide the detailed information needed for full implementation of the most recent dose coefficients for specific radionuclides

<sup>7</sup> See OSWER Directive 9200.4-18, EPA’s Yucca Mountain standards at 40 CFR part 197, and the preamble to the 1993 revision of the 40 CFR part 191 standards [58 FR 66411, December 20, 1993].

<sup>8</sup> The Agency’s “Guidelines for Carcinogen Risk Assessment” (2005) provide age-specific adjustments for carcinogens with a mutagenic mode of action for chemical carcinogens. Regulatory applications for radioactive compounds have not been determined.

and organs. Factors and biokinetic models to support such calculations are anticipated in future ICRP publications but have not yet been released, so there is a lack of appropriate modeling and compliance tools now available.

Furthermore, in order to provide the complete set of tools for calculating dose to different population age groups under ICRP 103, the Agency would need to update *Federal Guidance Report No. 13, Cancer Risk Coefficients for Environmental Exposure to Radionuclides*. However, the Federal Guidance Technical Report Working Group under the Interagency Steering Committee on Radiation Standards has convened to update these reports and the first draft could be available by the end of 2014. As such, these data could be available prior to any proposal of a revised standard. Thus, the analysis that relies on the most recent science (ICRP 103) could be conducted in a timely manner consistent with the time necessary for a rulemaking.

A third option would be to establish a dose limit but not to specify the ICRP basis for implementation. Under this approach, the details of implementation would be left to the NRC. NRC is beginning a comprehensive review of its regulations with the long-term view of adopting ICRP 103, which is likely to take a number of years. During this transition period, it may be appropriate to allow NRC to determine which method of calculation should be used, taking into account the views of the public. This could also anticipate the use of future ICRP recommendations beyond ICRP 103. An example of this approach is EPA's standards for the proposed Yucca Mountain disposal facility.<sup>9</sup> The advantage of this approach is that it allows the flexibility to use updated ICRP information as soon as (but not before) it can reasonably be implemented on a large-scale. A drawback of this approach is that it leaves some uncertainty as to what risk level is represented by the dose limit. That is, a dose of 15 mrem can represent a slightly different level of risk depending on the specific radionuclides, exposure situation and dose-risk factors. Therefore, a dose of 15 mrem could, in the future, represent a

different level of risk than originally expected. The difference would likely be small unless there are major changes in our understanding of radiation risks. Recent scientific advances have primarily influenced the understanding of risks from specific radionuclides to specific organs and to sensitive subpopulations—but have reinforced the overall dose-risk factors that serve as the major basis for most of EPA's radiation regulations and policies.

Finally, it is important that the economic impacts of any change in the dose methodology be carefully considered and acknowledged. The NRC staff has considered cost-benefit considerations in providing its recommendation to the NRC Commissioners for *Options to Revise Radiation Protection Regulations and Guidance with Respect to the 2007 Recommendations of the ICRP* (Dec 18, 2008). This paper identifies the inefficiencies with industry meeting the requirements using two different methods (40 CFR part 190 requirements are incorporated into 10 CFR part 50 Appendix I design objectives). This being the case, any change from the ICRP 2 approach to more contemporary dosimetry methodologies could yield a cost savings for the industry. The Agency is interested in receiving any data that are available on these potential cost savings.

In summary, the Agency is seeking input from the public on options that should be considered to update the radiation dosimetry for the standard. The range of options identified for consideration are: (1) Revise the dose limits to an “effective dose” standard using ICRP 60 methodology; (2) Revise the dose limits to an “effective dose” standard using ICRP 103 methodology; and (3) Specify a dose limit and leave the decision regarding methodology to NRC. We welcome comments on these options, on additional options that we have not identified, and on factors that should be considered in selecting and implementing a dose methodology.

#### 6. Questions for Public Comment

With the aforementioned as background, the Agency is seeking input on the following questions:

a. *If a dose standard is desired, how should the Agency take account of updated scientific information and methods related to radiation dose—such as the concept of committed effective dose?*

b. *In updating the dose standard, should the methodology in ICRP 60 or ICRP 103 be adopted, or should implementation allow some flexibility? What are the relative advantages or*

*disadvantages of not specifying which ICRP method be used for the dose assessment?*

**C. Issue 3—Radionuclide Release Limits.** The Agency has established individual limits for release of specific radionuclides of concern. Based on a concept known as collective dose, these standards limit the total discharge of these radionuclides to the environment. The Agency is seeking input on: Should the Agency retain the radionuclide release limits in an updated rule and, if so, what should the Agency use as the basis for any release limits?

#### 1. Why is this issue important?

The radionuclide specific release standards established in 40 CFR 190.10(b) set a limit on the total discharge of long-lived radionuclides released to the environment. These limits ensure that the environmental impacts of these radionuclides on the human population have a limited effect throughout the duration of their existence in the biosphere.

#### 2. What do the existing standards say on this issue?

The standards at 40 CFR 190.10(b) specify: “The total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle, per gigawatt-year of electrical energy produced by the fuel cycle, contains less than 50,000 curies of krypton-85, 5 millicuries of iodine-129, and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year.”

Excerpts from the 1976 FES (*Final Environmental Statement*, 1976, Vol. 1, p. 5), indicate the Agency's rationale and the regulatory facilities of concern in mandating this second set of environmental standards: “Finally, although fuel reprocessing plants are few in number, they represent the largest single potential source of environmental contamination in the fuel cycle, since it is at this point that the fuel cladding is broken up and all remaining fission and activation products become available for potential release to the environment.” Other parts of the nuclear fuel cycle emit much less of the radionuclides subject to 40 CFR 190.10(b) because the releases to the environment come after the fission process. Thus reprocessing facilities and, to a lesser extent, nuclear power plants are the focus of 40 CFR 190.10(b). The Agency developed this portion of the standard specifically to address the potential environmental burden associated with the resulting long-lived

<sup>9</sup> We provided similar discretion to NRC in our amendments to the Yucca Mountain standards. While we specified that the Department of Energy (DOE) must use ICRP 60 methodologies to project doses in its long-term performance assessment, we stated that NRC could permit the use of future dosimetric systems, as long as they were issued by consensus organizations, adopted by EPA into Federal Guidance, and consistent with the effective dose equivalent methodology first established in ICRP 26 and continued in ICRP 60. See 40 CFR part 197, Appendix A.

radionuclides and to ensure that the risk associated with any long-term environmental burden is incurred only in return for a beneficial product: electrical power. Furthermore, the Agency stated that “attention to individual exposure alone can result in inadequate control of releases of long-lived radionuclides, which may give rise to substantial long-term impacts over the lifetime of the radionuclide.”

The Agency based the limits for plutonium-239 and other alpha-emitters on emissions levels that could be achieved with best available control technologies. The limits for krypton-85 and iodine-129 relied on control technologies demonstrated on a laboratory scale, but not yet in actual use by 1975. Other long-lived radionuclides considered for regulation under this portion of the standard (i.e., tritium and carbon-14) ultimately were not included because appropriate control technologies were either not feasible or unavailable.

### 3. What has changed and how are those changes relevant?

The Agency developed the existing standard under the assumption that U.S. commercial reprocessing would be available. However, for policy and economic reasons, reprocessing never achieved the expected scale, and no commercial reprocessing plants are currently operating in the U.S. As of the drafting of this ANPR, however, there is renewed interest in Congress and the industry regarding the possibility of reprocessing as evidenced by testimony during hearings of the President’s Blue Ribbon Commission on America’s Nuclear Future. The broader nuclear industry is anticipating growth, with applications for new nuclear power plants submitted to the NRC and the start of construction at two power plant sites. Additionally, if the nation chooses to control carbon emissions from power generators, the number of nuclear power plants operating in the U.S. may increase further.

### 4. What policies and approaches are relevant?

The release limits were defined to limit exposures to populations wider than those in the immediate vicinity of a facility. Over the intervening decades, protection standards for individuals have become preferred, with collective dose considered less useful for assessing the risks of a given activity. Particularly in cases where extremely small doses combine with extremely large populations, collective dose can give a misleading view of the overall impact of an activity (and impact on individuals),

based on statistical estimates of the number of future health effects. Collective dose should thus be used with caution. For example, it can be used to provide meaningful comparisons of alternatives for a proposed action (e.g., in facility design).

Since the development of the release limits was motivated largely by concerns about emissions from reprocessing facilities, prospects of spent nuclear fuel reprocessing conducted both nationally and internationally may have a bearing on reconsideration of this issue.

There have been active reprocessing facilities in 15 countries, including the U.S., although some of these facilities were more research-oriented as opposed to commercial reprocessing facilities. Of the current operating facilities, the most widely known are the facilities at Sellafield (United Kingdom) and La Hague (France), which constitute the first and second leading producers globally for krypton-85. Both facilities discharge krypton-85 directly to the environment. Efforts at these plants are made to control the releases of iodine-129, and tracking the levels of this radionuclide over the years has shown decreasing emissions relative to reprocessing production quantities.

It is also useful to examine the experience of implementing the release limits in practice. While EPA sets the part 190 standards, the NRC has the responsibility to implement and enforce them for its licensees. Its requirements for licensees are found in 10 CFR part 20, “Standards for Protection Against Radiation,” specifically: 10 CFR 20.1301(e), which requires compliance with 40 CFR part 190, and 10 CFR 20.2203(a)(4), which further requires reporting of radiation levels or releases in excess of the standards in 40 CFR part 190. However, neither provision describes how to demonstrate compliance with 40 CFR part 190, although NRC has issued guidance to licensees for light water reactors in Generic Letters (GL) 79-041, GL79-070 and NUREG-0543 (ADAMS Accession No. ML081360410).

In anticipation that spent nuclear fuel reprocessing may again be pursued in the U.S., the NRC directed its former technical advisory committee, the Advisory Committee on Nuclear Waste and Materials (ACNW&M), to define the issues most important to the NRC concerning fuel reprocessing facilities. The ACNW&M published the results of their effort in NUREG-1909, “Background, Status, and Issues Related to the Regulation of Advanced Spent Nuclear Fuel Recycle Facilities.” The following excerpt from NUREG-1909

summarizes the ACNW&M’s finding regarding 40 CFR part 190: “Of particular relevance to fuel recycle is 40 CFR 190.10(b) which limits the release of krypton-85 and iodine-129 from normal operations of the uranium fuel cycle. Because fuel reprocessing is the only step of the nuclear fuel cycle that could release significant amounts of these radionuclides during normal operations, these limits are effectively release limits for the fuel reprocessing gaseous effluent.” (NUREG-1909, p.134) Other issues identified by the ACNW were: (1) Meeting the standard with available technologies may not be feasible; (2) limits on releases of carbon-14 and tritium may need to be considered; (3) the cost-benefit analysis for collective dose in 40 CFR 190.10(b) should be reconsidered; and (4) their belief that the existing regulation does not include fabrication of fuels enriched with plutonium or actinides other than uranium.

### 5. What compliance history exists for the current standards?

The Agency has reviewed compliance issues for these standards and has found challenges with determining and enforcing compliance. Without the operation of a reprocessing plant(s), there is little likelihood of exceeding the existing standards for the fission products krypton-85 and iodine-129. The basis for this statement is that both of these radionuclides are fission products (the result of the fission reaction occurring in the nuclear reactor) contained within the fuel rods at the nuclear power plants, and the fission products cannot escape unless the metal cladding around the fuel pellets ruptures during use or storage after removal from the reactor. During normal operations, the failure rate of cladding is insignificantly small. Uranium mining and milling, uranium conversion, uranium enrichment and fuel fabrication facilities do not generate these radionuclides since no fission reaction occurs during these processes.<sup>10</sup> Thus, only nuclear power plants and potential reprocessing facilities need to be considered when determining compliance with krypton-85 and iodine-129 limits.

NRC implements 40 CFR 190.10(b) through its oversight and inspection authorities for its licensees found in both 10 CFR part 20 and 10 CFR part 50. Specifically, 10 CFR part 20 includes the requirement that licensees comply

<sup>10</sup> Fuel fabrication facilities for mixed uranium-plutonium fuel (MOX fuel) could have some plutonium releases, but these would not be anticipated to approach the current limit.

with 40 CFR part 190. Technical specifications for commercial nuclear power plants are found in Appendix I of 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities." These specifications provide annual dose objectives for nuclear power plants that are considered "As Low As [is] Reasonably Achievable" (ALARA). The ALARA objectives are 3 mrem/year for liquid effluents and 5 mrem/year for gaseous effluents. The NRC has stated that, ". . . it was feasible for a licensee to inherently show compliance of 40 CFR part 190 limits by meeting the dose objectives in 10 CFR part 50 Appendix I."<sup>11</sup> The NRC staff has reviewed a sampling of effluent reports from 1981 to 2005, to assess the levels of krypton-85, iodine-129 and plutonium-239 and other transuranic alpha emitters released from operating nuclear power plants. Their findings were that these levels, on an annual unit of gigawatt-year of electrical energy produced, were significantly less than the limits in 40 CFR part 190. The standards apply to the industry's release of certain radionuclides proportional to the amount of electricity generated. Thus compliance relies on annual nationwide emissions for all applicable uranium fuel cycle facilities. If there were a case (such as multiple reprocessing plants) where the implementing agency considered that overall emissions were exceeding the standard, then the regulator may find it necessary to apportion or divide the standard to make it applicable to individual facilities. Further guidance may be necessary in order to detail a method for apportioning this standard. This uncertainty, and the difficulty in making and enforcing regulatory decisions about which facilities must undergo upgrades to meet the standards, makes implementing the standards extremely difficult at best if the situation arises where the entire uranium fuel cycle emissions are approaching the regulatory limit. EPA's goal in any revision of the standards is to ensure adequate public health protections, while providing appropriate flexibility to implementing agencies.

#### 6. What aspects of the issue are most important and what options are available to address this issue in revised standards?

The Agency determined in the development of 40 CFR part 190 that

<sup>11</sup> NRC Letter from Margie Kotzalas, MOX Branch Chief to Ron Fowler; Subj: Response to Concerns Regarding Ensuring Compliance with 40 CFR part 190. Sept. 24, 2008.

these standards would be important in reducing the environmental dose commitments for persistent radiological contaminants, and still considers this a desirable goal. The radionuclides specified in these standards were identified as those that could potentially disperse and deliver doses to widespread populations as they migrate through the biosphere. However, the current form of the standards appears to be impractical to implement. Furthermore, few consider collective dose appropriate for risk calculations or for use as a regulatory basis because "the summation of trivial average risks over very large populations or time periods . . . [produces] a distorted image of risk, completely out of perspective with risks accepted every day." (NCRP, 1995) In more recent radiation regulations, we have relied instead on individual dose limits to limit exposures to the public, combined with effluent or concentration limits to protect specific environmental resources (e.g., 40 CFR part 197).

There are several options under consideration for this portion of the regulation:

(a) Eliminate this portion of the regulation and rely on other limits to provide protection of public health and the environment.

(b) Use the concept from the existing standards of limiting the environmental burden of long-lived radionuclides in the biosphere as a guide, and calculate equivalent standards that could apply outside individual facilities (e.g., reprocessing plants).

(c) Use risk or dose to a designated receptor to develop radionuclide specific standards that would apply outside a given individual facility.

(d) Any additional options considered technically sound and developed by other stakeholders.

#### 7. Questions for Public Comment

*a. Should the Agency retain the concept of radionuclide-specific release limits to prevent the environmental build-up of long-lived radionuclides? What should be the basis of these limits?*

*b. Is it justifiable to apply limits on an industry-wide basis and, if so, can this be reasonably implemented? Would facility limits be more practicable?*

*c. If release limits are used, are the radionuclides for which limits have been established in the existing standard still appropriate and, if not, which ones should be added or subtracted?*

#### D. Issue 4—Water Resource Protection. How should a revised rule protect water resources?

##### 1. Why is this issue important?

Ground water and surface water are valuable resources necessary to maintain human life and healthy ecosystems now and in the future. Uranium fuel cycle facilities have the potential to release radioactive materials and contaminants that can get into surface water or ground water. EPA believes it better to take measures that prevent water contamination than to subsequently have to clean up the contamination.

##### 2. What does 40 CFR part 190 say? What is the technical basis?

The existing standard for nuclear power operations does not include a separate provision for protection of water resources at or geographically near these facilities. The FES (*Final Environmental Statement*, 1976, Vol. 1, p. 66) cites the rationale for not including water-specific standards: ". . . liquid pathway releases from these facilities result in much smaller potential doses than do noble gas releases [air releases]. Detailed studies of several specific facilities have revealed no actual dose to any individual from this pathway as great as 1 mrem per year." Thus, the Agency determined at that time that ground water contamination at these facilities was not likely to be a pervasive problem.

##### 3. What has changed and how are those changes important?

Ground water contamination has occurred at a number of nuclear power plants<sup>12</sup> and other uranium fuel cycle facilities.<sup>13 14</sup> The primary radionuclide responsible for ground water contamination at power plants is tritium, for which the Agency has established a Maximum Contaminant Level (MCL) of 20,000 picocuries/liter (pCi/L) for drinking water. Tritium is a radioactive isotope of hydrogen that can replace one of the stable hydrogen atoms in the water molecule, thus

<sup>12</sup> U.S. Nuclear Regulatory Commission (NRC). *Leaks and Spills of Tritium at U.S. Commercial Nuclear Power Plants, Revision 6* (Washington, DC: 2010).

<sup>13</sup> U.S. General Accounting Office (GAO). *Nuclear Waste Cleanup, DOE's Paducah Plan Faces Uncertainties and Excludes Costly Cleanup Activities*. GAO/RCED-00-96. (Washington, DC: 2010).

<sup>14</sup> U.S. Nuclear Regulatory Commission (NRC). *Environmental Assessment for the Renewal of U.S. Nuclear Regulatory Commission License No. SNM-1227 for AREVA NP, Inc. Richland Fuel Fabrication Facility*. (Washington, DC: 2009).

producing tritiated water. In the environment, tritiated water behaves very similarly to ordinary water. Tritium levels as high as 3.2 million pCi/L have been reported to the NRC in the ground water at some nuclear power plants. These elevated levels of tritium in ground water at these plants have prompted the NRC to create two specialized task forces to examine the issue. The task forces did not identify any instances where the public's health was impacted but did nevertheless recommend modifications to a number of regulatory documents.

Because of these releases to ground water at these sites, and related investigations, the Agency considers it prudent to re-examine its initial assumption in 1977 that the water pathway is not a pathway of concern. At this time the Agency has not developed formal options for this issue. Ground water monitoring is currently conducted at all facilities subject to NRC requirements established in 10 CFR parts 20 and 50, so the economic impact of potential provisions for ground water protection is largely undefined at this time, and the Agency is interested in estimates of potential costs. If the Agency proceeds with proposing options for either surface or ground water protection, then it would conduct a cost-benefit analysis for this issue.

#### 4. What policies and approaches are relevant?

When considering water resources, the Agency must determine whether there is a need to protect the resource and what protection is appropriate. The Agency has numerous authorities to protect ground water and surface water from contamination, and an examination of the applicability of these authorities is appropriate.

*Ground water.* In the years after 1977 when 40 CFR part 190 was issued, EPA increased its efforts to address ground water contamination including implementing new statutory authorities such as Superfund, hazardous waste programs, protection of underground storage tanks and protection of sources of drinking water. In recognition of the growing importance of ground water and increasing threats of contamination, EPA first outlined a comprehensive approach to ground water protection in its 1984 *Ground Water Protection Strategy*. EPA, with review by many federal agencies through the Administration's review procedures, replaced that strategy in July 1991, with another one titled *Protecting the Nation's Ground Water: EPA's Strategy for the 1990s—The Final Report of the*

*EPA Ground-Water Task Force.* That strategy is still in effect.

Consistent with part D of the July 1991 strategy, EPA implements a policy that "the Agency will use maximum concentration limits (MCLs) under the Safe Drinking Water Act<sup>15</sup> as "reference points" for water resource protection efforts when the ground water in question is a potential source of drinking water. Water quality standards, under the Clean Water Act, will be used as reference points when ground water is hydrologically connected to surface water ecological systems. Where MCLs are not available, EPA Health Advisory numbers or other approved health-based levels are recommended as points of reference. If such numbers are not available, reference points may be derived from the health-effects literature where appropriate. The strategy also notes that "[r]eaching the MCL or other appropriate reference point would be considered a failure of pollution prevention."

Site clean-up and other remedial actions generally use the MCLs as a cleanup goal and also take other factors into account. In some cases, EPA institutes the level of protection by directly incorporating the numerical limits from the Safe Drinking Water Act (SDWA) MCLs into other regulations. The 1991 strategy states relative to cleanup that "[r]emediation will generally attempt to achieve a total lifetime cancer risk level in the range of  $10^{-4}$  to  $10^{-6}$  and exposures to non-carcinogens below appropriate reference doses."

EPA considered the issue of ground water standards for radionuclides most recently in the development of "Environmental Protection Standards for Yucca Mountain" (66 FR 32074, June 13, 2001). In this regulation the Agency states that "Ground water is one of our nation's most precious resources because of its many potential uses . . . When that water is radioactively contaminated, each of those uses completes a radiation exposure pathway for people. Ground water contamination is also of concern to us because of potential adverse impacts upon ecosystems, particularly sensitive or endangered ecosystems. For these reasons, we believe it is a resource that needs protection." (66 FR 32106) In this

regulation, consistent with the Agency's *Ground Water Protection Strategy*, EPA adopted levels consistent with the drinking water MCLs as a basis for protecting the ground water resource. It may be noted that the ground water protection standards were applied prospectively at Yucca Mountain, in the sense that potential contamination of ground water in the accessible environment would not be expected for many hundreds to thousands of years. As such, the radionuclides of most concern for geologic disposal would not necessarily be the same as for operating fuel cycle facilities.

EPA has the authority under the Atomic Energy Act to promulgate generally applicable environmental standards to limit radioactive materials in the general environment outside the facility. Thus, any ground water standard that would be promulgated as part of a revision of 40 CFR part 190 would be limited to application of these limits outside the facility boundary. The NRC's 2010 Groundwater Task Force identified contamination in the aquifers beneath several nuclear power plants, but found that most of the contamination had not left the boundaries of the facility. While the Agency would hope that no contamination is emitted from nuclear fuel cycle facilities, we realize that this statement is a goal and may not reflect actual operating facilities. However, the Agency believes that it would be prudent to include limits to protect against migration of the contamination outside the fence line. Including a ground water standard would also bring the regulation more in line with other Agency regulations and policy goals.

*Surface water.* Industrial wastewater discharges to surface waters are generally prohibited under Section 301 of the Federal Water Pollution Control Act (known as the "Clean Water Act" or "CWA"). Under Section 402 of the Act, however, a point source may be authorized to discharge pollutants into waters of the United States by obtaining a permit. These permits, which are issued by the EPA or a state that has an EPA-approved permit program generally provide two types of controls: (1) Technology-based limitations (based on the technological and economic achievability); and (2) water quality-based limitations (to achieve compliance with water quality standards). For most major industries, including the Primary Industrial Categories listed in 40 CFR part 122, Appendix A, the Agency has developed Effluent Limitations Guidelines (ELGs), pursuant to sections 301(b) and 304 of the CWA, which set the technology-

<sup>15</sup> The EPA national primary drinking water standards under the Safe Drinking Water Act (SDWA) set limits on radionuclide concentrations—Maximum Contaminant Levels (MCLs)—in community drinking water systems (40 CFR 141.66). These SDWA regulations do not apply directly to ground water not used as drinking waters. MCLs generally only apply to finished drinking water after treatment.

based limits for discharges from such industrial categories. Any CWA Section 402 permit for a facility with applicable ELGs would be required to include limits prescribed by those regulations. With the exception of discharges from the “Uranium, Radium and Vanadium Ores” subcategory of the “Ore Mining and Dressing Point Source” category (40 CFR part 440, Subpart C), technology-based limitations for radionuclides associated with industrial discharges have not been established in the existing ELGs. The “Steam Electric Power Generating ELGs” (40 CFR part 423) apply to wastewater discharges from plants primarily engaged in the generation of electricity for distribution and sale which results primarily from the use of nuclear or fossil fuels in conjunction with a steam-water thermodynamic cycle. Those ELGs do not include limitations for radionuclides. However, where an ELG does not apply to certain waste streams or pollutants discharged by an industrial discharger, the permitting authority must establish technology-based effluent limits on a case-by-case, best professional judgment basis. (40 CFR 125.3 (c)(3)).

CWA Section 303 directs states to adopt standards for the protection of water quality, including human health and aquatic life uses. In most cases where states have adopted water quality criteria for radionuclides, those criteria are intended to protect human health uses such as drinking water. Several states have also adopted radionuclide standards for livestock watering and narrative radionuclide standards for protection of wildlife and aquatic life. When a discharge is found to have a reasonable potential to cause or contribute to an exceedance of a state water quality criterion established under their standards, CWA Section 402 permits must include limitations intended to protect that standard (see 40 CFR 122.44(d)(1)).

The NRC's regulations governing the design of effluent control systems at nuclear power plants are provided in General Design Criterion 60, “Control of Releases of Radioactive Materials to the Environment” of Appendix A, “General Design Criteria for Nuclear Power Plants” in 10 CFR part 50. The criterion is to provide a “means to control suitably the release of radioactive materials” to the environment. NRC regulations in 10 CFR part 50, Appendix I provide numerical guidance that limit releases of radioactive material to “As Low As [is] Reasonably Achievable” (ALARA) and meet the criteria to control releases suitably. These Appendix I guides become requirements

that are incorporated in the nuclear power plant operating licenses, and are consistent with EPA standards at 40 CFR part 190.

During nuclear power plant operations, 10 CFR 20.1406, “Minimization of Contamination” requires that all licensees, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface. Also, 10 CFR 20.1501, “general” (radiological surveys) require licensees to perform subsurface surveys (i.e., soil and ground water surveys) to identify residual radioactivity. For decommissioning and license termination requirements, NRC establishes cleanup criteria in Subpart E of 10 CFR part 20, “Radiological Criteria for License Termination” that are consistent with EPA standards at 40 CFR part 190.

## 5. Questions for Public Comment

*The Agency is seeking input on the following aspects of this issue:*

*a. If a ground water protection standard is established in the general environment outside the boundaries of nuclear fuel cycle facilities, what should the basis be and how should it be implemented?*

*b. Are additional standards aimed at limiting surface water contamination needed?*

## 6. Technical support documents and background information

Several of the issues surrounding the establishment of ground water protection standards for radionuclides have been discussed and addressed by the Agency in previous rulemaking efforts, as well as in guidance documents published or available from the Agency. The notable citations have been included in the references for this document. See reference numbers 9, 10, 13, 14, 15, 16, 29 and 30.

*E. Issue 5: Spent Nuclear Fuel and High-Level Radioactive Waste Storage. How, if at all, should a revised rule explicitly address storage of spent nuclear fuel and high-level radioactive waste?*

### 1. Why is this issue important?

When the existing rule was issued, storage of radioactive materials at nuclear fuel cycle facilities was not explicitly identified as an activity covered by the standards. Some storage was expected as part of operations, but the issue did not seem to merit particular attention. Greater attention has been given to storage in recent years, particularly for spent nuclear fuel at power plant sites. In the 1970s,

extensive reprocessing of spent nuclear fuel was envisioned, and disposal capacity was expected to be available, precluding the need to store spent nuclear fuel or other wastes at power plant sites for extended periods of time. However, interim storage of spent nuclear fuel, especially on site at nuclear power plants, has become the norm and for longer time periods than originally expected. We are now considering whether the prospect of extended storage warrants additional provisions to clarify how the standards would be implemented over the extended storage period.

In addition, in reviewing the requirements in 40 CFR part 190 as they apply to spent nuclear fuel storage, we have realized that the applicability of the standards is not clear with respect to its relationship with 40 CFR part 191, which also contains provisions that address spent nuclear fuel storage. Given the greater interest in spent nuclear fuel storage, we are considering whether it is useful and appropriate to clarify, especially with respect to 40 CFR part 191, the applicability of 40 CFR part 190 to spent nuclear fuel storage operations at facilities in the uranium fuel cycle and to dedicated spent nuclear fuel storage facilities.

## 2. What does 40 CFR part 190 say? What was the technical basis?

The regulation at 40 CFR part 190 did not directly address storage activities at nuclear fuel cycle facilities. At that time, some storage of radioactive materials was occurring at various nuclear fuel cycle facilities as part of their normal operations. It was assumed that the spent nuclear fuel was to be stored in pools for cooling for about 18 months, following which it would be collected and transported to reprocessing plants to be recycled for additional energy generation (*Draft Environmental Statement*, 1975). A reprocessing facility would necessarily require some storage for both the input and output of its processes (e.g., spent nuclear fuel and high-level radioactive waste) to ensure efficient industrial operation. Given these conditions, and the fact that storage was *not excluded* from coverage in the current standard—whereas several other activities were exempted, including mining, transportation and disposal—we believe it is reasonable that any storage incidental to operations at a nuclear fuel cycle facility should be covered by 40 CFR part 190.

Similar ambiguity exists regarding whether dedicated storage facilities are covered by 40 CFR part 190. Whether or not such storage facilities fall within

this category is not addressed in the rule and long-term storage of spent nuclear fuel was not analyzed during the rule development.

### 3. What has changed and how are those changes important?

Some waste storage practices now in place were not anticipated when 40 CFR part 190 was first issued. The most significant of these involve spent nuclear fuel. With no nuclear fuel reprocessing occurring and no disposal facility opened, spent nuclear fuel is being kept at nuclear power plants—in steel-lined, concrete pools or basins filled with water (spent nuclear fuel pools) or in massive, airtight steel or concrete-and-steel canisters, casks and vaults (spent nuclear fuel storage casks or dry cask storage)—awaiting national policy decisions and programs on reprocessing and ultimate disposal.

The President's Blue Ribbon Commission on America's Nuclear Future summarizes the current storage situation succinctly: "Storage [of spent nuclear fuel (SNF) at power plants] is not only playing a more prominent and protracted role in the nuclear fuel cycle than once expected, it is the *only* element of the back end of the fuel cycle that is currently being deployed on an operational scale in the United States. In fact, much larger quantities of spent nuclear fuel are being stored for much longer periods of time than policymakers envisioned. . . ." (BRC *Final Report*, January 2012, p.33). The Commission's final report also recommends the development of one or more consolidated interim storage facilities for spent nuclear fuel (see BRC *Final Report*, January 2012, p. 32), which would join a number of existing independent spent nuclear fuel storage installations (ISFSIs) primarily at existing and decommissioned nuclear power plants. The *Administration's Strategy for the Management and Disposal of Used Nuclear Fuel and High-Level Radioactive Waste* (January 2013) is for the Administration, with the appropriate authorizations from Congress and with enactment of required legislation, to implement a program over the next 10 years that:

- Sites, designs and licenses, constructs and begins operations of a pilot interim storage facility by 2021 with an initial focus on accepting used nuclear fuel from shut-down reactor sites.
- Advances toward the siting and licensing of a larger interim storage facility to be available by 2025 that will have sufficient capacity to provide flexibility in the waste management system and allows for acceptance of

enough used nuclear fuel to reduce expected government liabilities. (Department of Energy "Strategy for the Management and Disposal of Used Nuclear Fuel and High-Level Radioactive Wastes", 2013, p. 2). Thus, the foreseeable future holds the potential for storage of significant quantities of spent nuclear fuel—more than envisioned in 1977—at power plants and perhaps at consolidated facilities designed and devoted to that purpose.

Currently, the NRC is updating its "Waste Confidence" rule to address feasibility of continued storage until a repository is available. Since storage has become a more prominent part of nuclear power plant operations in recent years and a topic of greater concern to the public, the Agency believes it is worthwhile to consider whether a revised rule should address the topic more directly.

### 4. What policies and approaches are relevant?

Some storage activities—at a minimum, storage of spent nuclear fuel and high-level radioactive waste at *disposal* facilities—are quite clearly covered under EPA's requirements in 40 CFR part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes." However, the applicability is described quite broadly: Those standards address "management . . . and storage of spent nuclear fuel . . . at any facility regulated by the Nuclear Regulatory Commission or by Agreement States, to the extent that such management and storage operations are not subject to the provisions of part 190 of title 40." (40 CFR 191.01) The statement could be construed to apply to facilities beyond disposal facilities, including at nuclear power plants.

In practice, therefore, the language ensures full coverage of spent nuclear fuel storage—regardless of which activities are deemed to fall under which rule—since any activity not covered under the uranium fuel cycle should be covered under 40 CFR part 191. Further, the dose limits in 40 CFR part 191 apply to *combined* doses from storage activities covered under both rules (40 CFR 191.03(a)). The applicable NRC regulations also take into account multiple co-located or nearby sources and activities, and apply dose limits for the public that are consistent with both 40 CFR part 190 and the storage provisions of 40 CFR part 191. NRC storage requirements apply to spent nuclear fuel, high-level radioactive

waste and certain reactor-related low-level radioactive waste at stand-alone facilities as well as some on-site storage at power plants (10 CFR part 72).

### 5. What aspects of the issue are most important and what options might be considered to address this issue in revised standards?

The evaluation and licensing of spent nuclear fuel storage—on site at nuclear power plants and at other storage facilities—has been implemented by the NRC. The NRC has taken steps to improve the security and safety of storage in recent years and is further evaluating what improvements can be made in light of the events in Fukushima. (See BRC's *Final Report*, p. 46) However, we recognize that the volume of spent nuclear fuel now being stored—and expected to be stored in coming decades—is much greater than what was expected to be entailed in the operation of nuclear power plants and perhaps also at other facilities. If the Agency decides to revise 40 CFR part 190, it is reasonable to ask whether such storage operations should be considered part of the fuel cycle under these standards (instead of 40 CFR part 191), as well as whether additional technical provisions are needed to protect the public from potential exposures from such activities.

We believe that the simplest approach would be to clarify that the nuclear fuel cycle standards cover storage operations at nuclear fuel cycle facilities—likely including interim storage facilities—under 40 CFR part 190. In essence, it would specify that the "fuel cycle" ends only when the spent nuclear fuel reaches a permanent disposal facility. Clarifying coverage under 40 CFR part 190 would also ensure that updated dosimetry and science in any revised rule would be applied to storage operations not conducted at disposal facilities, especially if 40 CFR part 191 is not revised within a comparable time frame.

If a revised nuclear fuel cycle rule were to explicitly cover storage, an additional question is whether further requirements need to be instituted to address the long-term aspects of storage now envisioned. It is important to note that the existing EPA and NRC regulations discussed in this section are aimed at management and storage operations. With extended storage (60 years or more beyond the licensed operating period), there is the possibility that future degradation of dry casks or repackaging could result in additional exposures or even releases of radioactive material. A clarification regarding the coverage of EPA's nuclear

fuel cycle regulations would provide additional incentive to monitor storage operations to take the necessary measures to ensure continuing compliance. We believe that such a clarification would not require assessment of future storage performance, nor would it inform policy decisions on whether long-term storage should be pursued. We believe that any storage operation would need to meet the same regulatory requirements whether it be during licensing, or at the end of its post-closure life, so that additional technical requirements should not be necessary. In this case, actual changes to 40 CFR part 190 text could be limited to applicability and/or in the definitions.

#### 6. Questions for Public Comment

*a. How, if at all, should a revised rule explicitly address on-site storage operations for spent nuclear fuel?*

*b. Is it necessary to clarify the applicability of 40 CFR part 190 versus 40 CFR part 191 to storage operations? Should the Agency clarify the scope of 40 CFR part 190 to also cover operations at separate facilities (off-site) dedicated to storage of spent nuclear fuel (i.e., should we clarify the definition of the “nuclear fuel cycle” to include all management of spent nuclear fuel up until the point of transportation to a permanent disposal site)?*

*F. Issue 6: New Nuclear Technologies—What new technologies and practices have developed since 40 CFR part 190 was issued, and how should any revised rule address these advances and changes?*

#### 1. Why is this issue important?

The existing standard, as well as any potential revised standard, applies to nuclear power operations. Since the promulgation of the existing rule, new technologies and processes have been developed.

2. What does 40 CFR part 190 say? What was the technical basis?

The existing rule was developed based on aspects of the nuclear energy industry that were in existence in the early 1970s. The 1976 FES stated: “In the United States the early development of technology for the nuclear generation of electric power has focused around the light-water-cooled nuclear reactor. For this reason the proposed standards and this statement will consider only the use of enriched uranium-235 as fuel for the generation of electricity.” (*Final Environmental Statement*, 1976, Vol. 1, p. 3) Thus, the existing standards apply specifically to the uranium fuel cycle.

The 1976 FES stated: “The final part (of the uranium fuel cycle) consists of fuel reprocessing plants, where the fuel elements are mechanically and chemically broken down to isolate the large quantities of high-level radioactive wastes produced during fission for permanent storage and to recover substantial quantities of unused uranium and reactor-produced plutonium.” (*Final Environmental Statement*, 1976, Vol. 1, p. 4)

The technical basis for the existing standard anticipated increases in nuclear power generation. The 1975 *Draft Environmental Statement* stated on p. 4: “. . . well over 300,000 megawatts of nuclear electric generating capacity based on the use of uranium fuel will exist within the next 20 years or by 1997. . . . This increase will require a parallel growth in a number of other activities that must exist in order to support uranium-fueled nuclear reactors.” Furthermore, the DES (p. 5) stated: “This technical analysis assessed the potential health effects associated with each of the various types of planned releases of radioactivity from each of the various operations of the fuel cycle and the effectiveness and costs of the controls available to reduce such effluents.”

3. What has changed and how are those changes important?

Although more than 30 years have passed since the 1976 FES first described the state of the industry for which 40 CFR part 190 applies, many of the concepts remain the same. However, the status of several of the nuclear technologies has changed if one considers the international experience. This section will briefly discuss the nuclear technologies currently under consideration in the context of whether the Agency considers the technology as pending, and whether it merits revising existing regulations.

The 1976 FES stated the following: “There are, in all, three fuels available to commercial nuclear power. These are uranium-235, uranium-233 and plutonium-239.” (*Final Environmental Statement*, 1976, Vol. 1, p. 3) However, fuels produced from the naturally occurring thorium-232 isotope are possible and are currently being considered internationally for use in reactors. When used as a fuel for a nuclear reaction, thorium is transmuted to uranium-233; however, conventional nomenclature has termed this reaction as the thorium fuel cycle. Although thorium-232 based fuel would be part of the nuclear fuel cycle, some in the industry may argue that this reaction, and the processes considered part of this fuel cycle, would not technically be covered by the Subpart B provisions in 40 CFR part 190 for the “Uranium Fuel Cycle,” and thus there are no applicable limits for the thorium fuel cycle. Additionally, for plutonium based fuels and their inclusion under 40 CFR part 190, the FES only stated that some commercial use of recycled plutonium in light-water cooled reactors is proposed for the near future.

Several new nuclear power processing technologies have been licensed by the NRC and other technologies are being explored. The technologies analyzed by the Agency are included in the table below.

TABLE 1—SUMMARY OF NEW NUCLEAR TECHNOLOGIES

Advanced Light-water Reactor Designs <sup>16</sup> .....	AP1000; ABWR; ESBWR; US EPR; US APWR.
Fuel Reprocessing Designs <sup>17</sup> .....	Aqueous; Electrochemical; OREOX.
Advanced Reactor Concept <sup>18</sup> .....	MOX-PWR; MOX-BWR; Thorium-PWR; <sup>19</sup> Thorium-BWR; Heavy Water; Gas-Cooled; Sodium Fast.

In the above table, the MOX-PWR, MOX-BWR, Thorium-PWR and

<sup>16</sup> Advanced Light-water Reactor Designs are light-water reactor concepts with formal designs either approved or under review by the Nuclear Regulatory Commission.

<sup>17</sup> Fuel Reprocessing Designs are designs for reprocessing spent nuclear fuel using various chemical and mechanical reduction techniques.

<sup>18</sup> In the context of this table, Advanced Reactor Concepts are designs where the concept is available, but no U.S. designs have been approved for commercialization purposes.

Thorium-BWR are light-water reactors

<sup>19</sup> Thorium fuels have been used in the past both in small scale reactors in the U.S. (Fort St. Vrain and Peach Bottom), and overseas. Several countries are renewing efforts to use thorium as the base fuel for new reactors with India making new thorium reactors a major goal of its nuclear program.

(LWRs) that would operate with either mixed oxide (i.e., plutonium as well as uranium) or thorium fuels. The heavy water, gas-cooled, and sodium fast reactor concepts do not use light water for their moderator and/or coolant: heavy-water reactors (HWRs) use deuterium oxide ( $D_2O$ ) as the neutron flux moderator and can use either heavy water or light water as coolant (the Canada Deuterium-Uranium reactor (CANDU) is probably the most widely used heavy water reactor). Gas-cooled reactors usually use graphite as their moderator, and usually use helium as coolant, but can also use carbon dioxide. Finally, sodium fast reactors differ from LWRs. In a fast reactor, the fission chain reaction is sustained by fast neutrons, and thus does not need a neutron moderator. Also, because water acts as a neutron moderator, it is not usually used as a coolant in a fast reactor; rather, the coolant is a gas or a liquid metal, such as sodium or lead.

Although the list above does include some advanced reactor designs that are improvements to previous versions of LWRs (considered originally in the existing standard), these technologies may need to be given greater consideration in a potential revision to 40 CFR part 190 as design details regarding effluent contaminants are developed.

The regulation at 40 CFR part 190 specifically indicates it is restricted to the uranium fuel cycle for electricity production. As mentioned above, the use of thorium as a fuel in power reactors is being pursued by other countries and could also be used in the U.S. Thorium-232 is fertile material, that is, it cannot be used in the reactor directly but needs to be irradiated by neutrons in a uranium fuel reactor first in order to transmute it to fissile uranium-233 that can it be used as fuel in a reactor. As such, a thorium fuel cycle could also be considered as simply a variant of the uranium fuel cycle. However, to remove any potential ambiguity as to the limit of 40 CFR part 190, it may be useful to broaden the scope of 40 CFR part 190 to include all power generation technologies using nuclear fission.

Another new technology class being considered for commercialization within the U.S. is the Small Modular Reactors (SMRs). The term SMR refers to the size, or amount of energy generated by these reactors. They have been defined by the International Atomic Energy Agency as nuclear reactors generating 300 MW of electricity or less. The SMRs under development utilize traditional LWR designs, but also envision non-

traditional water reactor or non-water reactor designs, with the common feature being that of a smaller reactor. These designs would contain smaller amounts of fuel, thus posing smaller safety and associated hazards than those of traditional 1000 MW reactors or larger. Some small reactor designs envision placing compact reactor modules relatively deep underground and operating them without refueling for the entire plant life. Other countries have already begun building floating nuclear power plants based on small reactors. These plants can be docked at remote locations to deliver power to ground-based installations on shore. These designs could be used for generating electricity in isolated areas or producing high-temperature process heat for industrial purposes. The NRC expects to receive applications for staff review and approval of some of these designs in the near future (see [www.nrc.gov/reactors/advanced.html](http://www.nrc.gov/reactors/advanced.html)).

As mentioned earlier, this class of reactors potentially utilizes varying existing technology concepts at a smaller scale. The Agency could consider how to address this class of reactors in the future, in an updated rule, because of its projected growth.

#### 4. What policies and approaches are relevant?

The Agency limited the existing standards to the uranium fuel cycle and to light-water reactors, based on the state of the industry at the time. The Agency is considering whether the existing standards need to be revised to address new nuclear technologies that have been developed or may come on line in the near future, and, if so, which technologies should be considered.

#### 5. What aspects of the issue are most important and what options might be considered to address this issue in revised standards?

There are a couple of key considerations in determining the importance of new nuclear technologies. The first consideration is that any potential standard revision must provide protection from radiation emitted from new nuclear technologies. The Agency would need to develop standards for any new technology being commercialized if it is not already covered by the existing standards. The correction may be as simple as a definition change, but even the definition change could necessitate an analysis to identify if the existing standard appropriately protects the public from environmental releases from the new technology. The analysis may also be significantly more complex

if the new technology to be commercialized uses different radionuclides as a fuel and produces fission products in proportions which are different from those typical of LWRs. Even in the event that the fission products are similar in nature to those in the existing standard, the new technology could change the effluent concentrations of fission products significantly.

An example of this would be the commercialization of the thorium fuel cycle. Although the thorium is transmuted to uranium-233 for fission, the resulting fission products are projected to have a different composition from those generated by uranium-235. The fuel requirements for the thorium fuel cycle also require higher concentrations of enriched uranium and/or plutonium and would potentially yield larger amounts of low-level wastes. The Agency may have to conduct a review to determine what, if any, analyses would need to be conducted for the thorium variant.

The second consideration is that any potential revision must provide clarity on environmental requirements for new nuclear technologies. This is an important factor so that the industry will be able to properly plan and complete design criteria. The nuclear power industry has become more efficient, and new technologies have been developed for some aspects of the uranium industry. Many in the nuclear industry have spoken of the significant growth that may occur if constraints on carbon emissions come into existence.<sup>20</sup> Developing applicable radiation protection standards for future technologies now could provide regulatory certainty for the nuclear industry.

We recognize that the technologies discussed above, or other concepts being researched, may be at different stages of development. Some may be relatively close to commercialization, while the horizon for development and adoption of others may be much longer. While we believe it is appropriate to be forward-looking in gathering information to consider as part of a rulemaking that could adequately

<sup>20</sup>In response to major climate change initiatives proposed by Congress, the Nuclear Energy Institute has stated “Two major analyses issued in 2009 of the House version of the bill (H.R. 2454) make the case that significant nuclear energy provisions are necessary to achieve U.S. greenhouse gas emission reduction goals.” The Energy Information Administration issued *Energy Market and Economic Impacts of H.R. 2454, the American Clean Energy and Security Act of 2009*. The Environmental Protection Agency released *EPA Analysis of the American Clean Energy and Security Act of 2009* (H.R. 2454).

address future technologies, we acknowledge that it may be premature to address certain of these technologies in a rule before their potential implications and impacts are well understood. Therefore, the Agency could potentially address new technologies by using one of several approaches. These approaches include:

a. Review the technologies that are available in the U.S. and propose potential revisions only if they are not addressed by our existing standard.

b. Review technologies and anticipated near-term technologies that are available in the U.S. and propose revisions if these technologies are not addressed by our existing standard. Near-term technologies would have to be defined, but could be viewed as technologies anticipated to be commercialized within the next 10–30 years.

c. Review internationally available and anticipated near-term technologies and propose revisions if they are not addressed by our existing standard. This approach would consider foreign technologies that could be adopted in the U.S.

## 6. Questions for Public Comment

The Agency is seeking input on the following aspects regarding this issue:

a. *Are there specific new technologies or practices with unique characteristics that would dictate the need for separate or different limits and do these differences merit a reconsideration of the technical basis for 40 CFR part 190?*

b. *Should the Agency develop standards that will proactively apply to new nuclear technologies developed in the future, and if so, how far into the future should the Agency look (near-term, mid-term, etc.)?*

c. *In particular, do small modular reactors pose unique environmental concerns that warrant separate standards within 40 CFR part 190?*

## G. Other Possible Issues for Comment

If revised, the Radiation Protection Standards for Nuclear Power Operations may also address any number of issues identified during the public comment period. We will consider the comments submitted in response to this ANPR as we consider revision of the existing standards.

## III. What will we do with this information?

This Advance Notice of Proposed Rulemaking is being published to inform stakeholders, including federal and state entities, the nuclear industry, the public and any interested groups, that the Agency is reviewing the

existing standards to determine how the regulation at 40 CFR part 190 should be updated and soliciting input on changes (if any) that should be made. This action is not meant to be construed as an advocacy position either for or against nuclear power. EPA wants to ensure that environmental protection standards are adequate for the foreseeable future for nuclear fuel cycle facilities. As noted earlier, we believe the existing standards remain protective of public health and the environment; however, we believe that the issues mentioned above are sufficient to warrant a review and collection of public input on whether some portions of the standards need to be updated.

If the Agency does revise 40 CFR part 190, then the Agency would follow procedures outlined in the AEA and the APA and publish a proposed rule in the **Federal Register**. Comments received on this ANPR would be considered in the development of a proposed rule and would be used by the Agency to provide a clearer understanding of science, technology, or other concerns and perspectives of stakeholders. However, the Agency will not respond directly to comments submitted to this ANPR. The public would have the opportunity to submit written comments on any proposed rule that might be developed.

## IV. Statutory and Executive Order Reviews

Under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this is a “significant regulatory action” because the action raises novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not propose or impose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various statutes and Executive Orders that normally apply to rulemaking do not apply in this case. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders as applicable to that rulemaking.

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Dated: January 24, 2014.

**Gina McCarthy,**  
Administrator

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[Docket No. 131203999-4061-01]

RIN 0648-XD020

### Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule.

**SUMMARY:** NMFS proposes to implement an annual catch limit (ACL), harvest guideline (HG), annual catch target (ACT), and associated annual reference points for Pacific sardine in the U.S. exclusive economic zone (EEZ) off the Pacific coast for a one-time interim harvest period of January 1, 2014, through June 30, 2014, and to set annual harvest levels, such as overfishing limit (OFL), available biological catch (ABC), annual catch limit (ACL), for Pacific sardine for the whole calendar year 2014. This rulemaking is proposed according to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP), and reflects the proposed change to the starting date of the annual Pacific sardine fishery from January 1 to July 1 as published in the **Federal Register** on December 23, 2013. The proposed 2014 ACT or maximum directed HG is 19,846 (mt). Based on the seasonal allocation framework in the FMP, this equates to a first period (January 1 to June 30) allocation of 6,946 mt (35% of ACT). This rulemaking also proposes an adjusted directed non-tribal harvest allocation for this period of 5,446 mt. This value was reduced from the total first period allocation by 1000 mt for potential harvest by the Quinault Indian Nation as well as 500 mt to be used as an incidental set aside for other non-tribal commercial fisheries if the 5,446 mt limit is reached and directed fishing for sardine is closed. This rulemaking is intended to conserve and manage the Pacific sardine stock off the U.S. West Coast.

**DATES:** Comments must be received by March 6, 2014.

**ADDRESSES:** You may submit comments on this document identified by NOAA-NMFS-2013-0180 by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to

[www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2013-0180](http://www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2013-0180), click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- Mail: Submit written comments to William W. Stelle, Jr., Regional Administrator, West Coast Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115-0070; Attn: Joshua Lindsay.

- Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

#### FOR FURTHER INFORMATION CONTACT:

Joshua Lindsay, West Coast Region, NMFS, (562) 980-4034.

**SUPPLEMENTARY INFORMATION:** During public meetings each year, the estimated biomass for Pacific sardine is presented to the Pacific Fishery Management Council’s (Council) Coastal Pelagic Species (CPS) Management Team (Team), the Council’s CPS Advisory Subpanel (Subpanel) and the Council’s Scientific and Statistical Committee (SSC), and the biomass and the status of the fisheries are reviewed and discussed. The biomass estimate is then presented to the Council along with the calculated overfishing limit (OFL), available biological catch (ABC), annual catch limit (ACL) and harvest guideline (HG), along with recommendations and comments from the Team, Subpanel and SSC. Following review by the Council and after hearing public comment, the Council adopts a biomass estimate and makes its catch level recommendations to the National Marine Fisheries Service (NMFS). Each year NMFS then implements regulations that set the annual quota for the Pacific sardine fishing year that currently begins January 1 and ends December 31.

However, on December 23, 2013 NMFS published a proposed rule (78 FR 77413) to change the start date of the 12-month Pacific sardine fishery from January 1 to July 1, thus changing the fishing season from one based on the