

**U.S. Nuclear Regulatory Commission Staff's Comments
on the U.S. Environmental Protection Agency's Advance Notice
of Proposed Rulemaking
for 40 CFR Part 190, 79 FR 6509**

(February 4, 2014)

General Comments:

The U.S. Nuclear Regulatory Commission (NRC) staff appreciates the opportunity to provide input to the U.S. Environmental Protection Agency (EPA) on the issues and questions posed by the Advance Notice of Proposed Rulemaking (ANPR) for Title 40 of the *Code of Federal Regulations* (40 CFR) Part 190, published in the *Federal Register* on Tuesday, February 4, 2014. The NRC is currently considering potential revisions to its radiation protection standards in the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 and to those reactor design objectives concerning radioactive effluents in 10 CFR Part 50, Appendix I. The most recent Commission direction to the staff was issued on December 17, 2012, and may be found in the NRC Agencywide Documents Access and Management System (ADAMS)¹ at ADAMS Accession No. ML12352A133.

Issue Specific Comments:

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?

- 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?*

Comments:

The NRC staff believes that 40 CFR Part 190 regulations should continue to be expressed in terms of dose. While recognizing that other EPA programs use a risk metric, such metrics are used in the context of goals to be achieved, rather than limits which must be complied with, and below which the As Low As Reasonably Achievable (ALARA) principle (see 10 CFR 20.1003, definition of ALARA) is applied. As such, there may be a potential for confusion if the standard were expressed in terms of risk.

Activity and dose are objective quantities that have physical reality and can be measured. By contrast, risk has different meanings to different entities and individuals. Although the standards

¹ Access publicly available documents online in the NRC Library at: <http://www.nrc.gov/reading-rm/adams.html>. To search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at: 1-800-397-4209, 301-415-4737, or by e-mail to: pdr.resource@nrc.gov.

should be based on the degree of protection afforded to public health and safety (including an adequate margin of safety), the standards should be expressed in activity and/or dose.

The NRC “Standards for Protection Against Ionizing Radiation” (10 CFR Part 20) currently use the term “Total Effective Dose Equivalent” as the basis for occupational and public dose limits (see 10 CFR 20.1003, definition of Total Effective Dose Equivalent). The NRC staff is currently examining possible updates to the NRC standards, including the use of the terminology, “Effective Dose,” which is one of the recommendations of the International Commission on Radiological Protection (ICRP) Publication 103 (2007). The NRC staff also notes that the approach of integrating internal and external exposures has been incorporated into international standards, such as the International Atomic Energy Agency General Safety Requirements Volume 3, which is co-sponsored by other international organizations involved in health protection, such as the World Health Organization.

Moreover, the NRC would have the primary role in the implementation of any generally applicable environmental standard promulgated by the EPA, as NRC regulation 10 CFR 20.1301(e) requires that the NRC licensees comply with the 40 CFR Part 190 standards. As such, if EPA were to adopt a risk limit in 40 CFR Part 190, the NRC would need to expend additional resources (e.g., training staff and developing guidance documents for both staff and licensees) to implement such a risk based approach. The NRC staff believes that licensees’ compliance with 40 CFR Part 190 is greatly facilitated by use of dose, rather than translating such compliance to risk.

The ANPR notes that the relationship between dose and risk has changed since the time when 40 CFR Part 190 was originally promulgated, and asks whether this is a rationale for using risk as the updated standard. While further changes are possible, we are skeptical that such changes outweigh the benefit in the generally applicable standards being expressed in the units in which compliance will be demonstrated. Expressing the exposure outcome as risk would seem to be an unnecessary additional step and a source of additional uncertainty and error. Dose limits are also more appropriate from an inspection and enforcement standpoint as they provide a defined threshold for the NRC, as regulator, and for the regulated community. Finally, the NRC staff observes that it is becoming increasingly important in a globalized marketplace to use standards which can be directly compared with other national and international standards, which are expressed in terms of dose.

The concept of risk has been used extensively by the NRC in the regulatory framework for civilian uses of nuclear materials. Such a risk informed performance based approach to regulation includes consideration of the likelihood of exposure, in addition to the likelihood of adverse health effects, assuming that exposure occurs. Thus, if risk were considered for use in the 40 CFR Part 190 standards, it should take into account the likelihood of exposure. More information can be found at: (<http://www.nrc.gov/about-nrc/regulatory/risk-informed.html>)

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

- 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?*

Comments:

The NRC staff believes that any revised standard should take account of the updated scientific information and methods related to radiation dose. The Commission, in giving direction to the NRC staff, specifically noted that the staff should develop a regulatory basis to align with the most recent methodology and terminology for dose assessment. The NRC staff is currently preparing an Advance Notice of Proposed Rulemaking (Part 20 ANPR) concerning a potential revision to its radiation protection regulations in 10 CFR Part 20. The Part 20 ANPR, which seeks input from the public, the regulated community, and other stakeholders, is a critical step in the NRC staff's development of the Commission directed regulatory basis. Specifically, the Part 20 ANPR will seek input on aligning the NRC's regulations concerning dose methodology and terminology with the recommendations set forth in the ICRP Publication 103. The regulatory basis will be submitted to the Commission as a voting matter.

Information is now available that allows consideration of both male and female genders, and age specific anatomical and physiological data on the normal biological variability among humans, and information on children. The NRC's Part 20 ANPR will seek input on whether NRC's regulations on radioactive effluents, with respect to the public dose limit, should be revised to use an age and gender averaged approach, with the goal of providing a more realistic representation of a member of the public that explicitly includes consideration of the presence of infants and children within the population.

The NRC staff recommends, that to the extent feasible, the radiation dosimetry of any new rule should be maintained reasonably current, keeping in mind that it will take several years to complete a rulemaking effort, and advances in radiation dosimetry may occur during (or following) any rulemaking effort. Although ideally the standard should be maintained reasonably free of the details involved with the method of calculation, in reality this may not be possible (e.g., if the units of measurement change).

In the current situation, the dose standard in 40 CFR 190 is based on organ and whole body doses. The international recommendations for, as well as the science of, radiation dosimetry has changed several times since the promulgation in 1977 of the EPA standard. As a result, any new standard (or at least the units for the new standard) adopted by EPA should (at some point) be revised accordingly. At the same time, it should be recognized that the current

standard of 25 mrem to the whole body was originally accepted by the EPA as protective of the public and the environment. If EPA were to decide to change the standard to effective dose, as recommended by ICRP Publication 103, it is anticipated that an objective analysis would indicate there would be no significant difference in the level of protection afforded to the public. As a result, it is possible that the dosimetry methodology could be changed, with little or no change in the value of the standard, without having a significant impact on the level of protection afforded to the public.

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?

- 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?

Comments:

The NRC staff does not believe that it is necessary to maintain separate radionuclide release limits. The criteria associated with individual dose have proven to provide adequate protection, and the application of the ALARA principle has resulted in actual releases that are very small fractions of the limits. When 40 CFR Part 190 was promulgated, the projections for the nuclear fuel cycle included a significant number of power reactors, and the reprocessing of nuclear fuels. Those expectations have not become reality, for a variety of reasons. As noted by EPA in its ANPR, the majority of the potential releases of radionuclides of concern were associated with the reprocessing portion of the fuel cycle.

The concept of collective dose has been reassessed by the scientific community (see, for example, ICRP Publication 103) as being potentially misleading and generally inappropriate for purposes other than specific comparisons of different protection options. As a result, it is not possible for calculations (of future doses to individuals across the globe) to show whether radionuclide concentration limits actually provide any benefit over and above the protection afforded by the dose limits to individual members of the public.

Should commercial reprocessing of spent nuclear fuel resume in the United States, the NRC staff believe that the most appropriate approach would be for EPA to establish criteria for the releases from such facilities directly, rather than generic release criteria which apply across all facilities, as EPA has already done for other classes of facilities in the nuclear fuel cycle, such as uranium recovery facilities and disposal of high-level waste and spent fuel.

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

- 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?

Comments:

The NRC staff does not believe that a separate dose criteria is necessary in a revised rule to protect water resources. EPA's regulations in 40 CFR Part 190 were promulgated in 1977. Since that time, EPA has codified requirements for protection of drinking water under the Safe Drinking Water Act. Protection of these resources is now addressed in EPA's 40 CFR Part 141, National Primary Drinking Water Regulations. As a result, inclusion of additional groundwater rules in 40 CFR Part 190 would seem to be duplicative of the requirements in 40 CFR Part 141.

The NRC staff believes that an approach utilizing the summation of internal and external exposure from all sources and pathways, as currently provided in 10 CFR Part 20, is the most transparent and consistent approach to establishing adequate levels of protection under the Atomic Energy Act. Thus we believe that separate provisions for protection of water resources, or other media specific resources, would be duplicative, and are not necessary.

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?

- 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)?*

Comments:

The NRC staff does not believe that a revised rule would need to explicitly address the storage of spent nuclear fuel and high-level radioactive waste. The NRC's regulations include contributions from direct radiation and from effluent releases from spent fuel storage. In order to comply with NRC's regulations, the NRC's guidance to licensees includes contributions from direct radiation or from effluent releases from spent fuel storage. Effluents and direct radiation from a facility must comply with these requirements, and a dose criterion established under 40 CFR Part 190 would logically apply to all the contributions.

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?

- 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 (nearterm, mid-term, etc.)?*
- c. *In particular, do small modular reactors pose unique environmental concerns that warrant separate standards within 40 CFR part 190?*

Comments:

The NRC staff does not believe that any revised rule would need to separately address possible new technologies. The use of a standard that includes internal and external exposure from all pathways, as currently provided in 10 CFR Part 20, provides a unifying and transparent protection approach across the current and anticipated technologies and practices for nuclear technologies. While each new technology may have unique characteristics that would dictate specific licensing criteria, from a public protection perspective the effective dose remains the appropriate metric. Given the uncertainties in the possible new technologies, we do not believe it is appropriate, or necessary, for the EPA to consider separate criteria for new technologies at this time.

The EPA should clarify the distinction between the “nuclear fuel cycle” and the “uranium fuel cycle.” The term “nuclear fuel cycle” has a broad definition in 40 CFR 190.02(a), referring to “the operations defined to be associated with the production of electrical power for public use by any fuel cycle through utilization of nuclear energy.” The “uranium fuel cycle,” as defined in 40 CFR 190.02(b), appears to be a subset of the nuclear fuel cycle. It is somewhat confusing that 40 CFR 190.01 states “The provisions of this part apply to radiation doses received by members of the public in the general environment and to radioactive materials introduced into the general environment as the result of operations which are part of a nuclear fuel cycle,” whereas all of the standards in 40 CFR 190.10 apply only to the doses and releases “from the entire uranium fuel cycle.” Consider replacing the term “uranium fuel cycle” with “nuclear fuel cycle” since the second term includes both types of facilities.

The NRC staff notes that the current designs of small modular reactors (SMRs), for which the NRC may receive an application, are similar to the existing nuclear fuel cycle. Therefore, specific requirements for SMRs are not needed.