UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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Margaret M. Guerriero
U.S. Co-Chair, Great Lakes Water Quality Agreement, Annex 3
Director, Land & Chemicals Division
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SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSE TO THE NOMINATION OF RADIONUCLIDES AS CHEMICALS OF MUTUAL CONCERN UNDER ANNEX 3 OF THE GREAT LAKES WATER QUALITY AGREEMENT

Dear Ms. Guerriero:

On March 2, 2016, 110 environmental, health, and other advocacy groups submitted a nomination to the Great Lakes Executive Committee urging the Canadian and U.S. Governments to designate radionuclides as chemicals of mutual concern under Annex 3, Part B, section 2 of the Great Lakes Water Quality Agreement of 2012 (GLWQA). The U.S. Environmental Protection Agency (EPA) requested that the U.S. Nuclear Regulatory Commission (NRC), as the U.S. Government agency with expertise in this area, provide its recommendation to EPA on the nomination.

The NRC staff has reviewed the information in the nomination. The NRC staff has concluded that radionuclides should not be designated as chemicals of mutual concern. The basis for the NRC's recommendation is provided in the enclosure to this letter. As shown, the NRC has a robust regulatory regime that protects public health and the environment, and that provides for substantive transparency and public involvement. In addition, the enclosure shows that there is a sound technical basis to demonstrate that the NRC's regulatory program has been successful in ensuring that any radionuclide releases from NRC-licensed facilities into the environment have had a negligible impact on the water quality of the Great Lakes. Therefore, there is no practical benefit for designating radionuclides as chemicals of mutual concern.

The NRC appreciates the opportunity to share its conclusions and recommendations with the EPA. The NRC staff looks forward to continuing to work with you and your staff on this issue. Please keep me informed of any further developments regarding the nomination.

Sincerely,

Joseph G. Giitter
Division Director, Risk Assessment
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U.S. Nuclear Regulatory Commission

Enclosure: As stated
cc: See Mailing list

Mailing List, NRC Response to the Nomination of Radionuclides as Chemicals of Mutual Concern Under Annex 3 of the Great Lakes Water Quality Agreement

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ENCLSOURE

Basis for the U.S. Nuclear Regulatory Commission's Recommendation that Radionuclides Not Be Listed as Chemicals of Mutual Concern Under the Great Lakes Water Quality Agreement

Introduction

On March 2, 2016, 110 environmental, health, and other advocacy groups submitted a nomination to the Great Lakes Executive Committee urging the Canadian and U.S. Governments to designate radionuclides as chemicals of mutual concern under Annex 3, Part B, section 2 of the Great Lakes Water Quality Agreement of 2012 (GLWQA). The primary rationale supporting this nomination is set forth in a paper prepared by the Canadian Environmental Law Association (CELA). The CELA paper was an enclosure to the March 2, 2016 letter.

The U.S. Environmental Protection Agency (EPA) has requested assistance from the U.S. Nuclear Regulatory Commission (NRC) to evaluate the nomination of radionuclides as chemicals of mutual concern. Under the Atomic Energy Act of 1954, as amended (AEA), and the Energy Reorganization Act of 1974, Congress established the NRC to regulate the civilian use of radioactive materials in the United States. In this capacity, the NRC has regulatory authority over the use and transport of the radionuclides discussed in the petition. The NRC staff has reviewed the March 2, 2016 letter and the CELA paper provided in support of the nomination.

The nomination letter does not provide a sufficient technical basis to show that NRC regulations are not adequate for protecting the public and the environment; therefore, there is no practical benefit for designating radionuclides as chemicals of mutual concern. The NRC's regulatory program is fully protective of public health and safety, and the environment. Based upon existing data and current scientific evidence, reducing the NRC's dose limits to be more restrictive would not provide any safety or environmental benefit. Designating radionuclides as chemicals of mutual concern will unnecessarily increase regulatory burden without a commensurate increase in safety or environmental protection. In addition, the change in designation may unnecessarily increase public concerns by implying that current regulations are not protecting public health, safety and the environment. The NRC staff has concluded that radionuclides should not be designated as chemicals of mutual concern.

Regulatory Framework and Public Participation

The NRC has established a robust regulatory framework that protects the public and environment. This framework is composed of several components including regulations, licensing, guidance to the regulated community, oversight, enforcement, and emergency response. Applicants for an NRC license must meet the applicable regulatory requirements to obtain a license to construct and operate a nuclear reactor, and to otherwise use and possess

radioactive material.[1] These regulations are based on established engineering principles for safe plant design and operation. Before issuing a license, the NRC assesses the license application to ensure that safety measures are technically and scientifically sound, all requirements are met, and the appropriate safety systems and radioactive waste processing systems are in place to limit effluent releases to as low as reasonably achievable (ALARA) to protect the public and the environment.

When a nuclear power plant begins operation, the NRC assigns specially trained NRC staff as resident inspectors in permanent positions at the site. These NRC resident inspectors have unfettered access to all of the site information and provide continual oversight and inspection of the facility. The NRC inspectors ensure licensees meet the regulations and the terms of their license to operate safely. When violations are identified, the NRC takes the appropriate enforcement action. The NRC requires licensees to have an emergency response organization which conducts periodic drills to demonstrate readiness in case of a plant emergency. As part of its ongoing oversight, the NRC staff routinely collects and analyzes licensed facility operational experience. The NRC staff uses this information to make appropriate changes to its regulatory framework, on a generic basis, through rulemaking and the issuance of guidance, and on a case-by-case basis, to an individual facility's licensing basis (e.g., changes to license conditions).

Many components of the NRC's regulatory framework are transparent and include opportunities for public comment and participation in the NRC's regulatory process. For example, the NRC publishes all safety related inspection findings in the agency's public Web site. Furthermore, the NRC publishes all proposed, substantive regulations in the *Federal Register* for public comment and provides notice of its licensing actions on its public Web site and in the case of all reactor licensing actions, in the *Federal Register*. In addition, the NRC provides interested parties an opportunity to request a hearing for all license issuances and amendments.

Basis for the Establishment of NRC Regulatory Dose Limits

In their submittal, the petitioners state "there is no level of radionuclides below which exposure can be defined as 'safe;' therefore, very low levels of exposure can be significant." The petitioners may have come to this conclusion from their reading of the National Research Council of the National Academies report, "Health Risks from Exposure to Low Levels of Ionizing Radiation BEIR VII Phase 2," which is referenced in the CELA paper (p. 6, n.8). The NRC staff reviewed the same report. According to the staff's reading, the report does not assert that there is no safe level of exposure to radiation. In fact, the report does not address what is

[1] Although the regulation of nuclear power reactors, for purposes of radiological health and safety, and for security, is an exclusive NRC responsibility, the NRC may relinquish its authority to regulate the uses of certain categories of radioactive material to the States for various civilian purposes, such as medical uses and industrial radiography. Such authority is relinquished pursuant to an agreement entered into between the NRC and the Governor of the respective State, under Section 27 of the AEA. These states are known as Agreement States. The following States that border the Great Lakes are Agreement States: Minnesota, Wisconsin, Illinois, Ohio, Pennsylvania, and New York.

safe or not safe. Instead the report offers a nuanced look at the relationship between exposure to radiation and human health.

The National Research Council prepared BEIR VII, Phase 2, to advise the U.S. Government on the relationship between exposure to ionizing radiation and human health. The BEIR VII committee concluded that the higher the dose, the greater is the risk; conversely, the committee also concluded that the lower the dose, the lower is the likelihood of harm to human health. This is referred to as the linear-no-threshold hypothesis (LNT) which assumes that the cancer risk from radiation exposure continues in a linear fashion at lower doses below 0.1 sievert (Sv) (10 rem) without a threshold; that is, the LNT hypothesis assumes that a small dose has the potential to cause a corresponding small increase in risk to humans and only at zero dose will the risk be zero. It is important to note that the LNT hypothesis is a conservative model. In this regard, it is very difficult to establish the actual risk at very low doses because the risk of doses below 0.1 Sv (10 rem) over a lifetime is not known with certainty and could be zero.

Radiation protection scientific and standard-setting bodies such as the International Commission on Radiological Protection (ICRP) have used the LNT hypothesis in developing protective radiation practices for occupational and public exposure. The NRC has incorporated the recommendations from the ICRP and set the public dose limit in its regulations at 1 mSv (100 mrem).[2] In addition, NRC regulations require licensees to control releases from nuclear power plants such that the public doses are kept as low as is reasonably achievable (ALARA). The ALARA requirements are specified by regulation and the ALARA criteria is set well below the public dose limit. The NRC has established the ALARA criteria at 3 mrem from radionuclides released in liquid effluent from nuclear power plants.[3] In addition, all licensees are required to have monitoring programs for radioactive effluents as they are released from the plant and in the environment. As a result, actual doses to members of the public from nuclear power plant releases are about 100 times lower than the NRC public dose limit. These regulatory requirements result in a regulatory framework that ensures a very low risk from radiation exposure to members of the public. Because the existing regulatory framework ensures a very low risk from radiation exposure, the NRC believes there is no safety benefit for additional regulation of radionuclides as chemicals of mutual concern.

NRC Regulations on Material Discharges to the Environment

The NRC regulatory framework includes limits on the discharge of radioactive material to the environment and inspections to verify that licensees meet these limits. These discharges must be within the public dose limits and ALARA. To quantify the impact of these discharges, NRC regulations require that licensees conduct radiological environmental monitoring programs to measure radiation and radioactivity levels in the environment around each nuclear power plant. The radiological environmental monitoring program collects environmental monitoring data to verify the effectiveness of the plant systems that control the release of radioactive materials and

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[2] See 10 CFR 20.1301
[3] See 10 CFR Part 50, Appendix I

to demonstrate compliance with the public dose limits. The environmental monitoring program includes monitoring water and air samples at offsite locations where the highest concentrations of radionuclides are expected and measuring direct radiation from the plant using environmental dosimeters. In addition, the NRC requires licensees to sample and analyze various receptor pathways such as water, milk, soil, sediment, vegetation, and foodstuffs. The NRC requires licensees to report the results of the radiological environmental monitoring program annually to the agency. The licensee reports containing these results can be found at http://www.nrc.gov/reactors/operating/ops-experience/tritium/plant-info.html.

The radiological environmental monitoring programs for the plants in the Great Lakes region require monitoring several key receptor pathways. These include monitoring of the lake water at the land/lake interface, sources of drinking water, sediment from the lake shore line, local vegetation, foodstuffs, and the air. Recent data from these programs shows that a few samples detected very low levels of tritium that are within the regulatory limits near the discharge point of some nuclear power plants. The highest reported tritium concentration in the Great Lakes near a nuclear power plant was 1336 picocuries per liter (pCi/L), which is approximately 6.7 percent of the EPA drinking water standard of 20,000 pCi/L. The concentrations of other radionuclides measured in the environment that can be attributed to the operation of nuclear power plants are generally non-detectable. These results demonstrate that the regulatory framework effectively limits the discharge of material to ensure a very low risk of radiation exposure to members of the public, essentially resulting in a negligible impact to the environment. Because the existing regulations effectively limit the discharge of radioactive effluents from nuclear power plants, the NRC believes there is no safety benefit for additional regulation of radionuclides as chemicals of mutual concern.

Radioactive Material Discharges to the Environment from Normal Plant Operations

In the nomination letter, the petitioners expressed concern over the number of nuclear facilities near the Great Lakes because of material discharges into the lakes and the impact of those discharges. There are nine nuclear power plants licensed by the NRC operating on the shores of the Great Lakes. These plants, as well as others throughout the United States, have been operating safely in conformance with the NRC's regulatory framework, which includes limits on the discharge of radioactive effluents.

As part of the NRC's licensing process, each reactor licensee must demonstrate that the plant design and operation will meet all applicable NRC regulations. The NRC reviews the applicant's processes for releasing small quantities of radioactive materials to verify that all discharges will be within the ALARA criteria and well below the regulatory limits. These discharges are in the form of gaseous and liquid effluents. To facilitate operating below the limits, plants establish operating procedures to control radioactive effluents. To verify that discharges are below the limits, plants report the quantities of radionuclides released to unrestricted areas annually. Nuclear power plants, including those located in the Great Lakes Region, through their design, monitoring equipment, and operating procedures have been controlling the releases of radionuclides into the environment to levels within the ALARA criteria as well as within

regulatory limits. The radiological effluent reports submitted annually by licensees show that, over the past 40 years, the overall quantity of radioactive materials in gaseous and liquid effluents discharged from nuclear power plants in the United States are well below public health and safety limits and have, in fact, decreased significantly. Figures 1 and 2 below show the overall trend of radioactive releases from the nuclear power industry from 1976 to 2015. Figure 1 shows the industry median of the radioactivity from mixed fission and activation products (MFAPs) such as iodine-131 and cobalt-60 released in liquid effluents has decreased by 99 percent for pressurized-water reactors (PWRs). For boiling-water reactors (BWRs), the radioactivity released in liquid effluents have decreased by 99.99 percent. Figure 2 shows the industry median for the noble gas radioactivity released in gaseous effluents has decreased by about 99.9 percent for both reactor types. These trends demonstrate that the regulatory framework is protective because the plants' processes to control the release of material are effective to ensure that releases are kept as low as reasonably achievable. Thus, any additional regulation would not provide a safety or an environmental protection benefit.

Figure 1

Long-term trend of MFAP in liquid effluents

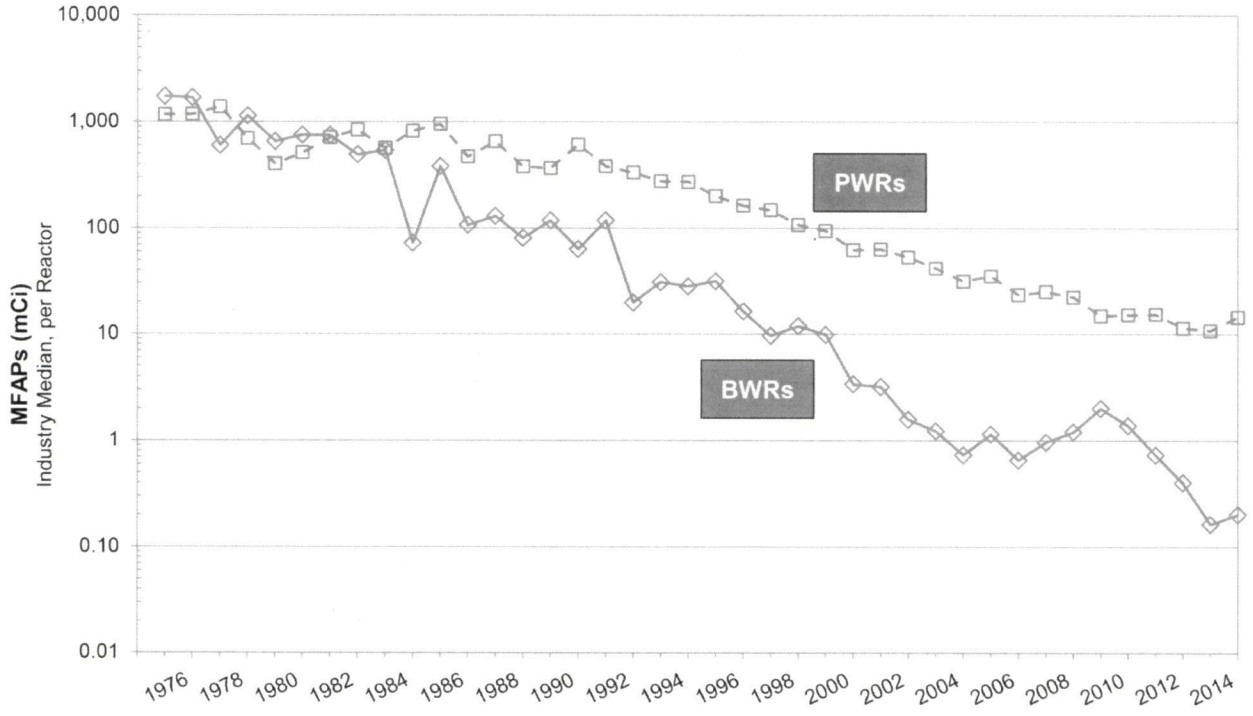
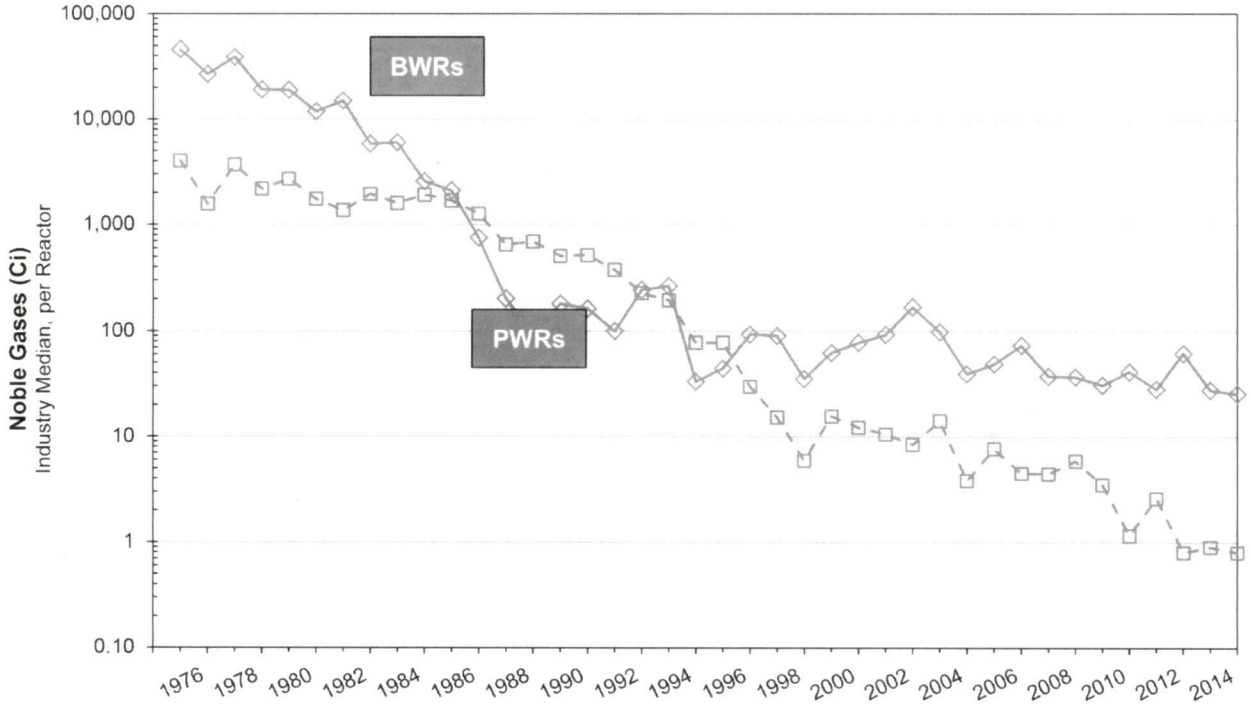


Figure 2

Long-term trend in noble gas effluents



NRC Oversight to Verify Licensee Compliance with Regulations

The NRC continually monitors every nuclear power plant through its comprehensive oversight program called the Reactor Oversight Process (ROP). Through the ROP, the NRC verifies that licensees are complying with the regulations and the requirements in their operating license. The ROP integrates the NRC's inspection, performance indicator, assessment, and enforcement programs for operating reactors. The NRC has at least two resident inspectors who are permanently located at each site and who perform inspection activities on a continual basis. In addition, inspectors based in the NRC's regional offices periodically perform more specialized inspections at the site. The plants provide these inspectors with unfettered access to the plant so that inspectors can review all aspects of plant design and operation. The NRC makes the results of every inspection at each site publically available through the NRC public Web site. The ROP takes the inspection results and performance indicator information, which are based on plant operations, and assesses the information to determine the level of oversight each plant requires. As a licensee's performance declines, the NRC increases the level of oversight. In addition, the inspection findings may result in the NRC taking enforcement action against the licensee.

The NRC has specialized inspectors who inspect all radiological protection aspects of the plants' design and operation. These inspectors are experienced and receive in-depth training in radiation safety. As part of the ROP, they review all the plants' radiation protection programs.

They also review the results of the radiological effluent and environmental monitoring programs to confirm that radioactive effluent discharges to the environment and public doses remain ALARA and below the regulatory limits. Therefore, the ROP provides continual oversight with a focus on radiation safety and the NRC believes that additional regulation would not provide a safety benefit.

Minimizing the Risk of a Large Radioactive Release from a Reactor Accident

In the nomination letter, the petitioners expressed concern that the number of facilities results in a high probability of accidents that release higher amounts of radionuclides. The NRC regulatory framework requires that plants be designed with multiple independent and redundant safety systems. Plants must also be designed with multiple barriers including a reactor containment to prevent a radioactive release. These features provide what is called a "defense-in-depth" approach that reduces the probability of reactor accidents and prevents a large release. To further minimize the risk of an accident, the NRC requires nuclear power plant operators to be highly trained and skilled personnel who undergo continual training and testing. This layered approach has been successful in ensuring that plants are designed and operated safely in the United States. In over 40 years of nuclear regulation in the United States, the most significant release of radioactive material occurred in 1979 during an accident at the Three Mile Island Nuclear Generating Station. The release was estimated to result in an average dose to a member of the public of about 0.014 mSv (1.4 mrem) which is significantly less than NRC's public dose limit of 1 mSv (100 mrem). The maximum dose that could have been received by anyone person located offsite was also estimated to be below the public dose limit of 1 mSv (100 mrem).

The NRC routinely collects and analyzes operational experience and uses this information to make changes to the regulatory framework to improve safety. Following the Fukushima Daiichi accident, the NRC used the lessons learned from the accident to enhance the safety of U.S. reactors. Using the lessons learned, the NRC conducted a systematic and methodical review of its regulations and processes to identify safety improvements. As a result, the NRC issued the Mitigation Strategies Order which required all U.S. nuclear power plants to implement strategies that will allow them to cope without their permanent electrical power sources for an indefinite amount of time. The strategies must keep the reactor core and spent fuel in the spent fuel pool cool, as well as ensure that the integrity of the thick concrete containment building surrounding each reactor is maintained. The NRC expects the mitigation strategies to use a combination of currently installed equipment, additional portable equipment that is stored onsite, and equipment that can be transported to the sites from support centers. Additionally, the NRC required plant licensees to install spent fuel pool level instrumentation, reevaluate certain areas such as flooding and earthquake hazards, and evaluate emergency preparedness staffing and communications.

Regulations for the Safe Transportation of Radioactive Materials

The March 2, 2016 letter also expressed concern with the risk associated with the transportation of radioactive materials. Thousands of shipments of radioactive materials (primarily medical isotopes) are transported safely on international and national routes each day. Radioactive shipments, which are transported by road, rail, sea, air, and inland waterways, can include smoke detectors, radioactive sources for medical and industrial uses, and other byproduct material generated during electric power generation. The safety of these shipments is maintained through the Federal regulations promulgated by both the U.S. Department of Transportation and the NRC, the primary agencies that share the responsibility of regulating the transportation of radioactive materials. The regulations, which are based on standards that have been established by the International Atomic Energy Agency (IAEA), require that the greater the potential risk posed by the radioactive contents, the more stringent the packaging and shipping requirements need to be. These requirements minimize the amount of radioactivity that could be released from a package involved in an accident. The safety standards established in the regulations provide an adequate level of control of the radiation, criticality, and thermal hazards to the public and environment that may be associated with the transport of radioactive materials. Since the establishment of the international standards over 50 years ago, there have been no known deaths or injuries to transport workers, emergency services personnel, or the general public in the United States as a result of the radioactive materials in transport, and any releases into the environment have been negligible. This record can be attributed to the proper packaging and transportation of radioactive material and the effectiveness of the transportation safety standards and regulations.

Conclusion

The NRC staff reviewed the March 2, 2016 letter and the associated CELA paper. The letter requested that the EPA designate radionuclides as chemicals of mutual concern in accordance with Annex 3 of the Great Lakes Water Quality Agreement. The NRC has reviewed the issues raised in the paper against the current regulatory requirements in order to identify possible gaps in the NRC regulatory framework. As discussed previously, the NRC has established a robust regulatory framework that is fully protective of public health, safety, and the environment. This framework is composed of regulations, licensing, guidance to licensees, oversight, enforcement, and emergency response. It also includes limits on radionuclide discharges and requires environmental monitoring to confirm that any discharges will remain both ALARA and below regulatory limits. The low levels of plant related radioactive materials in the environment, which has been decreasing, demonstrates that the regulatory framework is effective in protecting the public health and safety, and the environment. The nomination letter and the CELA paper do not present a technical basis that demonstrates that the NRC regulations are not adequate for protecting the public and the environment. Therefore, the NRC staff has concluded that radionuclides should not be designated as chemicals of mutual concern because the NRC already effectively regulates the use and transport of nuclear materials for civilian purposes.

With the comprehensive regulatory framework that effectively limits radionuclide discharges already in place, designating radionuclides as chemicals of mutual concern is unnecessary, would be unduly burdensome, and would not provide a safety or an environmental protection benefit.