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

October 13, 2023

Edwin (Ted) Smith
U.S. Co-Chair, Great Lakes Water Quality Agreement, Annex 3
Great Lakes National Program Office
U.S. Environmental Protection Agency
77 W. Jackson Blvd (G-9J)
Chicago, IL 60604

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSE TO THE RENOMINATION OF RADIONUCLIDES AS CHEMICALS OF MUTUAL CONCERN UNDER ANNEX 3 OF THE GREAT LAKES WATER QUALITY AGREEMENT

Dear Mr. Smith:

On May 16, 2022, the Canadian Environmental Law Association and Toxics-Free Great Lakes Binational Network submitted a nomination to the Great Lakes Executive Committee requesting that radionuclides be designated chemicals of mutual concern under Annex 3 of the Great Lakes Water Quality Agreement of 2012. 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 reviewed the information in the 2022 nomination and information submitted to support a similar nomination in 2016. The NRC staff concludes that radionuclides should not be designated as chemicals of mutual concern. The basis for this recommendation is provided in the enclosure to this letter. The enclosure shows that there is a sound technical basis to demonstrate that the NRC's regulatory program is adequate in ensuring that radionuclide releases from NRC-licensed facilities into the environment are monitored, controlled, and have a negligible impact on the water quality of the Great Lakes. Therefore, there is no practical benefit to designating radionuclides as chemicals of mutual concern.

The NRC appreciates the opportunity to share its conclusions and recommendation 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,

Signed by Franovich, Michael
on 10/10/23

Michael X. Franovich
Division Director, Risk Assessment
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission

Enclosure: As stated
cc: See Mailing list

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSE TO THE RENOMINATION OF RADIONUCLIDES AS CHEMICALS OF MUTUAL CONCERN UNDER ANNEX 3 OF THE GREAT LAKES WATER QUALITY AGREEMENT DATED: 10/13/2023

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DATE	8/16/2023	10/13/2023	9/27/2023

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Mailing List, U.S. Nuclear Regulatory Commission Response to the Renomination of Radionuclides as Chemicals of Mutual Concern Under Annex 3 of the Great Lakes Water Quality Agreement

Cc:

Christopher Korleski, U.S. Secretariat,
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BASIS FOR THE U.S. NUCLEAR REGULATORY COMMISSION'S RECOMMENDATION THAT RADIONUCLIDES NOT BE LISTED AS CHEMICALS OF MUTUAL CONCERN UNDER ANNEX 3 OF THE GREAT LAKES WATER QUALITY AGREEMENT

INTRODUCTION

The United States and Canada entered into the Great Lakes Water Quality Agreement (GLWQA, the Agreement) in 1972.[1] The U.S. Environmental Protection Agency (EPA) serves as the U.S. Government's agent for the Agreement. Over the years, the Agreement has been amended and its implementing procedures have been updated. The Agreement consists of 10 annexes of which one, Annex 3, "Chemicals of Mutual Concern," involves the protection of human health and the environment by seeking to reduce the anthropogenic release of certain chemicals (chemicals of mutual concern) into the waters of the Great Lakes.

The GLWQA provides a process by which individuals and organizations can nominate chemicals to be designated as chemicals of mutual concern. Under a process that was updated in 2021, the "Binational Screening Criteria for Nominated Chemicals of Mutual Concern under Annex 3 of the Great Lakes Water Quality Agreement,"[2] the EPA received, in 2022, a nomination for radionuclides to be designated as chemicals of mutual concern.[3] The EPA asked the U.S. Nuclear Regulatory Commission (NRC) to provide technical support in evaluating the material submitted for the nomination of radionuclides as chemicals of mutual concern.

In 2017, the NRC evaluated a similar request;[4] however, at that time the current screening criteria were not in effect. While the screening criteria are important and provide a logical approach for discerning if a chemical should be of mutual concern, the NRC's recommendation is not impacted by the criteria. The evaluation in this document, in combination with the NRC's 2017 evaluation, provides the basis for the NRC's recommendation that the U.S. Government not assent to the designation of radionuclides as chemicals of mutual concern under the GLWQA.

BACKGROUND

In 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

Enclosure

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1 "Protocol Amending the Agreement between Canada and the United States of America on Great Lakes Water Quality, 1978, as Amended on October 16, 1983, and on November 18, 1987, Signed September 7, 2012, Entered into force February 12, 2013," https://binational.net/agreement/full-text-the-2012-great-lakes-water-quality-agreement/

2 https://binational.net/2021/03/03/bsc-ncmc-ceb-pcspm/

3 "Renomination of Radionuclides as Chemicals of Mutual Concern under the Great Lakes Water Quality Agreement," May 16, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23178A157).

4 "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," January 24, 2017 (ADAMS Accession No. ML16335A057).

radionuclides as chemicals of mutual concern under Annex 3, Part B, section 2, of the GLWQA.

In 2017, after reviewing the nomination, the NRC staff concluded that radionuclides should not be designated as chemicals of mutual concern. The NRC's 2017 evaluation described how the agency regulates radionuclide releases to the environment originating from its licensees, in particular nuclear power plant licensees. The evaluation explained the NRC's regulatory framework and mechanisms for public participation in NRC decision-making; the basis for the NRC's limits on radiation exposure; the regulations on discharges of material, including radioactive material from normal nuclear power plant operations, to the environment; the NRC's oversight program to ensure that licensees comply with applicable requirements; how NRC requirements provide adequate protection against nuclear accidents; and regulations for the safe transportation of radioactive materials. Based on this evaluation, the NRC concluded that the petitioners did not provide a sufficient technical basis to demonstrate that the agency's regulations and practices were inadequate for protecting the public and environment from activities under its auspices. Therefore, in 2017, the NRC recommended that radionuclides not be designated as chemicals of mutual concern.

As documented below, in response to the 2022 renomination, the NRC has reviewed the potential for radionuclides to be designated as chemicals of mutual concern under the 2021 screening criteria and continues to make the same recommendation as in 2017 that they should not be so designated.

Overview of NRC Regulatory Framework

The health effects of radiation are intrinsically tied to the amount of radiation dose received and are typically divided into two general categories: deterministic effects and stochastic effects. Deterministic effects are known to occur at high levels of radiation exposure, as compared to the typical exposures received from background radiation,[5] and these types of effects do not occur below determinable threshold values. Examples of deterministic effects include, at the lower range of doses, skin reddening and cataracts, and, in scenarios involving significant radiation exposures, symptoms associated with acute radiation syndrome (e.g., nausea, detrimental impacts on blood composition and central nervous system function). The NRC's public radiation dose limits are very small percentages of the thresholds for deterministic effects; therefore, deterministic effects of radiation exposure are not expected to occur in members of the public.

Stochastic effects are probabilistic in nature, and the scientific community generally accepts that their risk of occurrence varies proportionately with radiation dose. More specifically, as the NRC staff explained in its 2017 evaluation, the relationship between exposure to ionizing radiation and human health is understood to be linear, in that at low doses, there is a correspondingly low risk of stochastic health effects, and for increasing dose, there is a linear increase in the risk of stochastic health effects. Furthermore, this relationship is understood to have no threshold below which the risk of health effects does not occur. This concept is known as the linear-no-threshold (LNT) model. The LNT model remains a hypothesis in large part because of the difficulty associated with confirming that observed health effects are in fact attributable to

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[5] In National Council on Radiation Protection and Measurements (NCRP) Report No. 160, "Ionizing Radiation Exposure of the Population of the United States," issued 2009, the NCRP estimated that the average person in the United States receives about 620 millirem (mrem) of radiation dose each year from all sources (i.e., both natural background radiation and manmade radiation sources). About 50 percent (310 mrem) of this dose is from exposure for medical purposes, and 0.1 percent (0.62 mrem) is attributable to effluents from nuclear power plants.

exposure to very low levels of ionizing radiation and not attributable to other factors that impact human health (e.g., environmental factors, genetic predisposition for certain diseases). Such a confirmation would require significant epidemiological studies as discussed in NCRP Commentary No. 27, "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection," issued in May 2018. Nevertheless, the NRC has determined that the LNT model continues to provide a sound regulatory basis for minimizing risk to unnecessary radiation exposure to both members of the public and radiation workers.

An important way that the LNT model is incorporated into the NRC's regulatory framework is by application of the as low as is reasonably achievable (ALARA) principle. In Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1003, "Definitions," the NRC defines ALARA as making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

The NRC primarily implements ALARA through its oversight activities; however, the ALARA principle permeates all NRC functions. For example, NRC regulations limit the amount of radioactive material that can be released to the environment, on a per nuclide basis, to ensure that the public dose limit is not exceeded. This limitation on the amount of radioactive material that can be released from nuclear power plants has resulted in significant reductions in the contribution of effluents to the background radiation dose, as described in the annual reporting of NUREG/CR-2907, "Radioactive Effluents from Nuclear Power Plants."[6] In addition to the regulations in 10 CFR 20.1101, "Radiation protection programs," that impose ALARA requirements on all NRC licensees, the regulations in 10 CFR 50.36a, "Technical specifications on effluents from nuclear power reactors," impose additional conditions on nuclear power plant licensees. These specifications are intended to keep releases of radioactive materials to unrestricted areas during operations to ALARA levels. Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," provides numerical guidance on design objectives and limiting conditions for the operation of nuclear power plants to meet the ALARA requirements.

NRC regulations require that nuclear power plant licensees survey the areas within the plant boundary and surrounding the plant to measure the amount of radioactive effluents released into these areas and to demonstrate compliance with applicable effluent limitations. Therefore, NRC nuclear power plant licensees must measure and control the amount of radioactive effluent as it is leaving the site (e.g., through plant effluent stacks or liquid discharge piping), and they must also evaluate the area surrounding the plant by conducting an environmental monitoring program. These two programs are typically called the radiological effluent monitoring and control program and the radiological environmental monitoring program, respectively. Implementation of these requirements is described in the licensee-specific technical specifications and, typically, further described in licensee-controlled documents, such as the offsite dose calculation manuals (ODCMs). Technical specifications are publicly available documents that are established when the NRC grants a license to a nuclear power plant, and they are maintained through the NRC's ongoing licensing activities (i.e., they cannot be

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6 https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr2907/index.html

changed without prior NRC approval). NRC regulations also require licensees to annually report the results of their effluent and environmental monitoring programs. Individual plant reports are publicly available through the NRC's public website[7] and are summarized in NUREG/CR-2907.

The NRC public dose limits and the allowable effluent release concentrations that are derived from those limits are set so as to completely avoid deterministic effects and to minimize the risk of stochastic effects to levels that are considered to be adequately protective of public health and safety.

Evaluation of the 2022 Renomination

In 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 the GLWQA. In 2021, the screening criteria for nominated chemicals of mutual concern were updated. Thereafter, in May 2022, the Canadian Environmental Law Association and Toxics-Free Great Lakes Binational Network (the petitioners) renominated radionuclides to be considered chemicals of mutual concern (the 2022 renomination). The petitioners submitted the 2022 renomination in accordance with the 2021 criteria. Table 1 shows the six criteria and their corresponding subparagraphs.

Table 1 Great Lakes Water Quality Agreement Chemicals of Mutual Concern Screening Criteria

Criteria	Corresponding Subparagraphs
TOXIC: Is the chemical substance toxic, persistent, and/or bioaccumulative?	a. Has the chemical substance been found to be toxic? b. Is the chemical substance persistent and/or bioaccumulative?
RELEASE: To what extent is the chemical substance released in the Great Lakes Basin?	a. Are there releases of the chemical substance to water or air? b. Are releases likely to increase in the future due to increasing manufacture, import, or use in Canada or the U.S.?
LEVELS: Are levels of the chemical substance harmful, or likely to become harmful, in the Great Lakes environment?	a. Are measured concentrations of the chemical substance in the Great Lakes environment (air, water, sediment, and/or biota) nearing, meeting or exceeding benchmarks or guidelines for protection of wildlife and humans, including fish consumption advisory levels, water quality standards, etc.? b. Are concentrations of the chemical substances in the Great Lakes environment (air, water, sediment, and/or biota) increasing, suggesting early action is warranted?
ROUTE OF EXPOSURE: Are the Great Lakes a significant route of exposure to humans or wildlife for this chemical substance? Are the impacts, or likely impacts, caused by routes of exposure via:	a. Great Lakes water? b. Great Lakes sediments? c. Great Lakes food web?
SCALE: Does the geographic scale of the levels of the chemical substance in the Great Lakes have binational significance?	a. Is the contamination currently, or likely to become, lakewide or multi-lake in scale as opposed to localized? b. Does the contamination have the potential to cause binational transboundary impacts?
MANAGEMENT: To what extent are the releases of the chemical substance controlled/managed?	a. Are programs and management actions for the chemical substance currently in place at the local,

[7] https://www.nrc.gov/reactors/operating/ops-experience/tritium/plant-info.html

Criteria	Corresponding Subparagraphs
	state/provincial, tribal, Indigenous, federal or international level? b. Are current actions adequate, and/or do gaps exist?

In the 2022 renomination, the petitioners state that radionuclides meet each of the criteria in Table 1 and, thus, should be considered chemicals of mutual concern. However, it is not clear that the petitioners are adequately characterizing the expected health effects of radiation at exposure levels that are representative of exposures received by members of the U.S. public, or that would result from the small levels of radioactive material in the environment of the Great Lakes.

Since its discovery, radiation exposure has been well studied. This focus increased as the scientific community attempted to understand the health effects of nuclear weapons testing and their use during World War II. The most reliable cancer incidence information regarding radiation exposure comes from studies of atomic bomb survivors. However, it is important to note that the doses to which these survivors were exposed far exceed the doses that members of the U.S. public receive from anthropogenic radiation, and this inconsistency introduces a significant difference in expected health outcomes. For example, in the U.S. National Research Council's Biological Effects of Ionizing Radiation (BEIR) VII report,[8] an excess cancer risk of less than 0.8 percent is associated with an acute dose equivalent of 10 rem (i.e., 10,000 mrem) to all organs of the body. Furthermore, for low linear energy transfer radiation (i.e., the type of radiation that typically results from the decay of radionuclides released from nuclear power plants), fractionation of the dose over weeks or even months is expected to reduce the excess cancer risk by a factor of 2 or more.

The public dose limit set by the NRC's regulations is 100 mrem per year. To obtain a numerical dose of 10 rem, a member of the public would have to be exposed at the NRC public dose limit for 100 years. As previously explained, nuclear power plant licensees must measure and report levels of radionuclides in and around the plant site. These reports indicate that members of the public are exposed to radionuclides at levels well below even the NRC limit—on the order of several millirem per year. Therefore, the excess cancer risk from exposure to radiation at nominal public dose levels resulting from U.S. nuclear power plant effluents can reasonably be expected to be a small fraction of 1 percent. While this is not zero risk, the NRC reasonably concludes that this level of risk adequately protects public health and safety.

The petitioners' characterization of the extent to which radioactive material is released to the environment, the extent to which the Great Lakes are a significant route of exposure to humans or wildlife, and the binational significance of the geographic scale of radionuclides in the Great Lakes environment does not comport with information that the NRC routinely collects from its nuclear power plant licensees. Figures 1 and 2 below provide visualizations of the reported historic median mixed fission and activation product (MFAP) and noble gas effluents from U.S. nuclear power plants. Effluents at these levels result in doses to members of the public that are within the NRC's ALARA criterion described above. Furthermore, while some radioactive effluents may contain radionuclides with long half-lives, no NRC licensee has discovered excessive deposition of these radionuclides through their environmental monitoring programs that are required by NRC regulations.

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[8] National Research Council. 2006. *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2*. Washington, DC: The National Academies Press. https://doi.org/10.17226/11340.

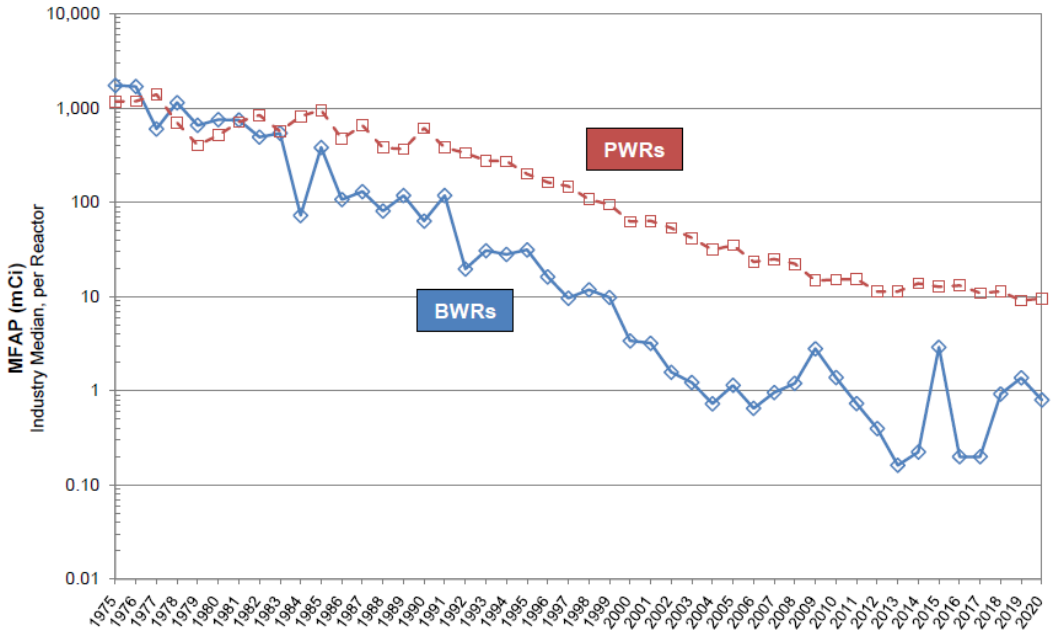

Figure 1 Long-Term Trend in Mixed Fission and Activation Products in Liquid Effluents for Boiling-Water Reactors (BWRs) and Pressurized-Water Reactors (PWRs) (Figure 3-16 excerpted from NUREG/CR-2907, Vol. 26, dated June 2023 [ADAMS Accession No. ML23164A219])

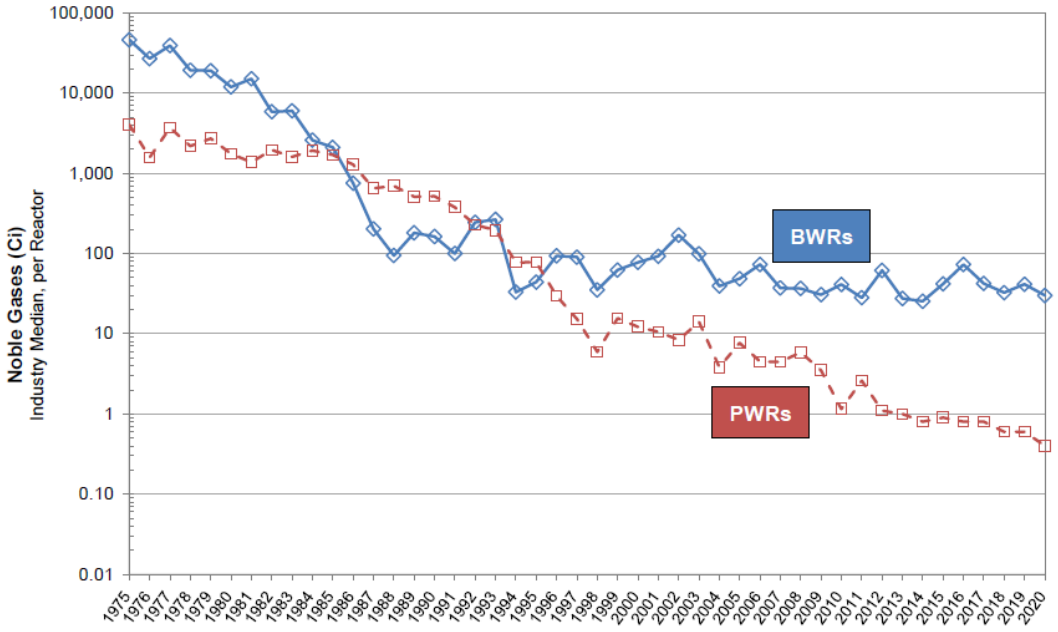

Figure 2 Long-Term Trend in Noble Gases in Gaseous Effluents for BWRs and PWRs (Figure 3-15 excerpted from NUREG/CR-2907, Vol. 26, dated June 2023 [ADAMS Accession No. ML23164A219])

Regarding the existing levels of anthropogenic radionuclides in the Great Lakes water, the NRC, as a technical organization, understands the desire for more data allowing further clarity. To the extent that such data can be obtained through stakeholder initiative, the NRC supports those

efforts. However, the NRC's standard of adequate protection, as implemented through its regulations and practices, ensures that members of the public are being protected from potential detrimental effects of activities that the NRC regulates. This approach necessitates that the NRC identify in a risk-informed manner requirements that ensure adequate protection of the public while enabling the regulated enterprise to exist. The NRC staff observes that in its 1997 report, which is cited by the petitioners in the 2022 renomination, the Nuclear Task Force of the International Joint Commission[9] concluded that the primary goal of monitoring is to demonstrate that the health, safety, and environmental requirements of a facility are being met, as dictated by the legislation of each country (i.e., the United States and Canada) applicable to its nuclear enterprise.

The NRC's position on the management of radionuclide releases to the Great Lakes from U.S. nuclear power plants is unchanged from that in its 2017 evaluation. As discussed in that evaluation, the NRC has established a robust regulatory framework that adequately protects public health, safety, and the environment. This framework is composed of regulations, licensing activities, 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 below regulatory limits and ALARA. The measured, low levels of radioactive materials in the environment related to U.S. nuclear power plants combined with the scientific consensus regarding the impacts of radioactive materials demonstrate that this regulatory framework is effective in protecting public health and safety and the environment. Therefore, radionuclides from the operation of U.S. nuclear power plants are not chemicals of mutual concern under the GLWQA.

Recommendation

The U.S. Government should not assent to the designation of radionuclides as chemicals of mutual concern under the GLWQA.

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9 International Joint Commission's Nuclear Task Force, "Inventory of Radionuclides for the Great Lakes," December 1997, https://ijc.org/sites/default/files/C131.pdf