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Bo Pham, Deputy Director
Division of Decommissioning, Uranium Recovery, and Waste Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Regarding: Issues Regarding Classification of Environmental Samples as 11e.(2) Byproduct Material and Request for Consideration for Inclusion of Additional Regulatory Language in Potential Upcoming Rulemaking

Dear Mr. Pham:

First, we would like to express our gratitude for meeting with us in late July to discuss issues associated with the conduct of certain actions by laboratories when assisting licensees with testing of samples containing 11e.(2) byproduct material. Thompson & Pugsley and Alexco Water and Environment, Inc. (AWE) represent a group of analytical laboratories and uranium recovery companies (herein, known as the 11e.(2) working group) to address issues raised by the United States Nuclear Regulatory Commission (NRC) Staff regarding the classification of environmental samples that may contain or constitute 11e.(2) byproduct material. On June 4, 2019, NRC Staff delivered a presentation during the 2019 National Mining Association's Uranium Recovery Workshop in Denver, Colorado, entitled *Status of NRC Inspection Program and Some Lessons Learned*. During this presentation, NRC Staff informed the workshop attendees that licensees of NRC possessing and/or using 11e.(2) byproduct material would be required to ensure that laboratories receiving environmental samples from such licensees must, themselves, be licensed to receive, possess, and use the samples. NRC Staff's rationale for this statement stems from two (2) basic facts:

- Unlike source material, NRC regulations do not provide general license for possession of small quantities of 11.e(2) byproduct material, thus possession of any quantity requires specific license per 10 CFR 40.3." (NRC, 2019). This is consistent with traditional statutory interpretation of the Atomic Energy Act of 1954 (AEA) that there is no *de minimis* amount of 11e.(2) byproduct material. PLEASE NOTE that while there appear to be grounds to question this interpretation, for purposes of this communication, such grounds are not relevant at this time;
- On October 5, 1993, NRC's Uranium Recovery Field Office issued letter to UR industry regarding the possession of tailings samples without a license:
 - Licensees were reminded to verify that recipient laboratories were licensed to possess byproduct material
 - 10 CFR 40.51 prohibits transfer of source or byproduct material to another person unless they hold a license for possession of byproduct material."

During this presentation, NRC Staff provided examples of what types of samples could be considered 11.e(2) byproduct material. The examples included: groundwater, surface water, air particulates, radon (environmental and flux), and bioassay samples if they contained radionuclides.

NRC Staff's, June 4, presentation was the first such communication regarding the need for laboratories to obtain licenses for environmental samples that industry was made aware of and raised several potential present and future regulatory questions. These unique and unforeseen challenges for laboratories include, but are not limited to:

- Regulatory Uncertainty – Some laboratories do not possess licenses for environmental samples. Are they now required to obtain licenses to possess, and use environmental samples even if a trace quantity of radionuclides is present?
- Ability to analyze samples within the laboratory facility.
- For some samples, it may be impossible to discern the natural radioactivity from byproduct material (i.e., air particulates, environmental radon, surface water, and groundwater).
- For industry, these technical analyses for 11e.(2) byproduct material are necessary for maintaining compliance with a variety of regulatory regimes arising from NRC/Agreement States, the United States Environmental Protection Agency (EPA), and States

The issue of environmental samples is made more perplexing due to the actual statement in the aforementioned 1993 letter. This letter actually states that “tailings” samples are 11.e(2) byproduct material and that special requirements are needed to receive, possess, and use these samples. However, NRC Staff's position that environmental samples are now equivalent to tailings samples is a new interpretation. Although the staff is correct regarding the lack of *de minimis* quantity of 11.e(2) byproduct material within applicable regulations, the health risks associated with environmental samples do not warrant the additional regulatory burden.

To address this issue, the 11.e(2) working group would like to offer the following options to NRC Staff for reducing the burden on laboratories and uranium recovery companies:

1. **Exemption/Exclusion** – EPA under 40 CFR 261.4(d) promulgated an exclusion for samples which reads, as follows:

(d) Samples. (1) Except as provided in paragraphs (d)(2) and (4) of this section, a sample of solid waste or a sample of water, soil, or air, which is collected for the sole purpose of testing to determine its characteristics or composition, is not subject to any requirements of this part or parts 262 through 268 or part 270 or part 124 of this chapter or to the notification requirements of section 3010 of RCRA, when:

NRC could promulgate a similar exemption/exclusion that with certain conditions that are specified in EPA sample exclusion. Such an exemption would provide regulatory certainty and relieve laboratories and uranium mining companies of a regulatory burden that does not further the protection of public health, safety, and the environment. This is an important example of how NRC Staff could solve this problem as the group would not be asking the agency to create a new

exemption; but rather, it is asking the agency to mirror an exemption already in use by a sister agency charged with a similar statutory mission of protecting public health and safety and the environment. This is permissible without amending the AEA, because NRC would still maintain active jurisdiction over all 11e.(2) byproduct material but would selectively choose to regulate it without the need for specific license requirements which, in this instance, provide no additional health and safety or environmental protection nor does it solve a newly identified health and safety or environmental problem;

2. **General License** – The NRC could promulgate a general license that would allow for the receipt, possession, and use of environmental samples. Such a license could include the necessary provisions regarding safe storage, transportation, and disposal to protect public health, safety, and the environment. This is permissible without amending the AEA as well because NRC would still maintain active jurisdiction over all 11e.(2) byproduct material but would selectively choose to regulate it without the need for specific license requirements which, in this instance, provide no additional health and safety or environmental protection nor does it solve a newly identified health and safety or environmental problem;
3. **Regulatory Issue Summary (RIS)** – The NRC could exercise regulatory discretion, either temporarily or long-term, and present the rationale in a RIS. A RIS, would provide regulatory certainty and relief from regulatory burden, while the agency develops a more permanent solution. Even if NRC Staff were to adopt Option #1 or #2, an interim RIS setting forth the agency’s intent to solve this problem would fill any regulatory gaps in its process.

Currently, NRC Staff is considering a Part 40 rulemaking to address *in situ* leach uranium recovery (ISR) facilities, since a similar rulemaking by EPA is not going to occur. This potential rulemaking may commence with a SECY paper to the Commission requesting a directive to proceed within a certain identified scope. The working group respectfully requests that a solution to this issue be included in such a SECY paper.

On behalf of the 11.e(2) working group, Thompson & Pugsley and AWE would like to thank the Commission and the staff for promptly addressing this issue. If you have any questions, please contact me at address or e-mail below.

Signed electronically /s/

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