

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

May 7, 2025

ALL AGREEMENT STATES
CONNECTICUT, INDIANA, WEST VIRGINIA

Subject: NATIONAL MATERIALS PROGRAM EFFORTS RELATED TO EXEMPT DISTRIBUTION LICENSE FOR CONSUMER PRODUCTS (STC-25-024)

Purpose: To inform the Agreement States, Connecticut, Indiana, West Virginia, Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards (NMSS), and NRC Regions I, III, and IV of the efforts across the National Materials Program (NMP) related to communications on how NRC approves licenses for exempt consumer products and outline how any new information on exempt consumer products will be shared moving forward.

Background: Recently there has been an increased interest in understanding the way in which the NRC approves licenses for exempt consumer products. This communication summarizes the numerous interactions between the Agreement States and the NRC and presents the current status.

Discussion: The Organization of Agreement States (OAS) requested an opportunity to discuss NRC's process for approving products under exempt distribution criteria with emphasis in those products licensed under 10 CFR 32.30, Industrial Devices. On September 16, 2023, during an NMP Champions Chat the NRC provided a presentation and addressed questions regarding the NRC, distribution of Exempt Products and the related regulations. At the August 2024, OAS Annual Meeting, a panel presentation focused on Agreement States concerns surrounding the use of exempt consumer products. Since then, NRC has given additional presentations and shared further details on how it approves licenses for exempt products, along with comprehensive information on devices authorized under 10 CFR 32.30 exempt distribution license including the Viken Detection Model Pb200e. For example, on September 25, 2024, during an NMP Champions Chat the NRC further discussed the distribution of exempt products with special focus on the review and evaluation process and the regulations governing the review.

In response to the ongoing conversations from the Champions Chat, the NRC modified the National Sealed Source and Device Registry (Registry) to include an active list of all the exempt product devices that have been approved by the NRC since the rule in 10 CFR 32.30 went into effect. On November 21, 2024, during the NMP Monthly call, the NRC reported on the changes to the Registry and the status of pending applications seeking approval under 10 CFR 32.30. Additionally, the NRC and Agreement States formed a Standing Committee (Committee) on Sealed Source and Device Expertise. This Committee will be a resource for collaboration surrounding technical evaluations of sealed sources or devices containing sealed sources and will meet on a quarterly basis. Applications for products falling under the exempt product licensing that requires sealed source and device evaluation may be discussed in the committee and shared with

Agreement State partners when involving new and/or emergent technologies approvals. The Committee will provide new information as necessary. If there are any further questions regarding exempt consumer devices or SSD, they may be submitted to the standing committee for review and response.

Additionally, OAS raised with the NRC a concern that aggregating exempt sources in 10 CFR 32.30 is addressed insufficiently. Specifically, OAS stated that it would be prudent to include in 10 CFR 32.30 a limitation on aggregating exempt sources, such as that found in 10 CFR 30.18(e). The NRC considers unnecessary incorporating the language of 10 CFR 30.18(e) into section 32.30. First, these respective regulations concern different regulatory frameworks, as 10 CFR 32.30 is geared towards the manufacturer or distributor of industrial devices and 10 CFR 30.18(e) is geared towards the user. Section 32.30 addresses the licensing requirements for certain industrial devices containing byproduct material while 30.18 exempts from licensing requirements those that possess byproduct material below the specified quantities. Furthermore, the limitation on aggregating exempt sources in 10 CFR 30.18(e) is meant to address multiple exempt quantities within an individual device that has not been evaluated or approved by the NRC. In contrast, devices licensed under 10 CFR 32.30 are evaluated and registered in the Sealed Source and Device Registry, and they undergo a licensing review that examines both normal use and potential misuse. If OAS believes rulemaking is necessary to modify the language in 10 CFR 32.30, 10 CFR 2.802 provides an opportunity to submit a petition for rulemaking.

I look forward to continuing to work with the Agreement States, OAS, and the NMP Champions to strengthen our partnership as co-regulators of the NMP.

If you have any questions regarding this correspondence, please contact me at (301) 287-0737 or the individual named below:

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Signed by Silberfeld, Dafna on 05/07/25

Dafna Silberfeld, Acting Director Division of Material Safety, Security, State and Tribal Programs Office of Nuclear Material Safety and Safeguards STC-25-024 National Materials Program Efforts Related to Exempt Distribution License for Consumer Products DATE May 7, 2025

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