

From: [Tapp, Katherine](#)
To: ["Matthew Arno"](#)
Cc: [Wu, Irene](#)
Subject: Question on Public Dose
Date: Wednesday, October 23, 2019 2:22:00 PM

Dr. Arno,

For the November 6th public meeting, could you plan to discuss how Exubrion's proposed dose release criteria complies with public dose limits in 10 CFR 20.1301(a)(2). Specifically, 10 CFR 20.1301(a)(2) requires the dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75, to not exceed 0.002 rem (0.02 millisievert) in any one hour. As stated in NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," animals that have been injected with a radioactive compound cannot be released until the veterinarian ensures that the dose that members of the public will receive from the animal is within the limits of 10 CFR 20.1301, which includes both the 100 mrem annual limit and the 2 mrem in any one hour limit. If possible, it would be beneficial to discuss how you are planning to demonstrate that your dose release criteria complies with this regulation at the November 6th meeting.

Please let me know if you have any questions.

Thank you,

Katie

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