UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

April 23, 2020

Brian L. Baker, Director
U.S. Department of Health and Human Services
Food and Drug Administration
109 Holton Street
Public Health Service, FDA
Winchester, MA 01890-1197

SUBJECT: TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* (10 CFR) 30.35(e)(2) and 30.35(f), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, MAIL CONTROL NO. 618552

Dear Mr. Baker:

By email dated April 7, 2020 (ML20105A106), in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.11(a), the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) requested a temporary exemption from the 3-year and 30-day deadlines in 10 CFR 30.35(e)(2) and 30.35(f), respectively.

In its request, FDA stated that it is seeking this exemption because strict conformance with the regulation requires signature from senior FDA management, and the ability to obtain the required approval and signature is delayed due to FDA's activities in response to the COVID-19 public health emergency (PHE).

10 CFR 30.35(e)(2) requires, in pertinent part, that at the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan (DFP) must be resubmitted with adjustments as necessary to account for changes in cost and the extent of contamination. The DFP was last adjusted in May 2017 and submitted as an attachment to a letter dated May 9, 2017. However, FDA asserts that completion of the evaluation of the cost adjustments and review by management is impacted by the PHE and requests an extension of this requirement.

FDA also requests an extension to comply with the requirement in 10 CFR 30.35(f) for the submission of financial instrument, a Statement of Intent, that is a signed original or a signed original duplicate. FDA posits that the amount of financial assurance will decrease based on the DFP and the Statement of Intent must match or exceed the DFP. Since the Statement of Intent is dependent on the evaluation of the DFP, FDA requests an extension of this requirement.

The exemption provision in 10 CFR 30.11(a) states:

> The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The NRC staff reviewed FDA's exemption request and finds that the criteria in 10 CFR 30.11(a) for requesting exemptions was met. The regulations for which FDA is requesting exemptions are:

- To extend the requirement for the submission of a DFP at intervals not exceeding 3 years included in 10 CFR 30.35(e)(2) to 90 days from the date of this letter.
- To extend the requirement for the submission of a revised financial assurance instrument included in 10 CFR 30.35(f) to 90 days from the date of this letter.

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 30. The NRC staff has determined that the granting of the requested exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The NRC finds that the regulations, for which exemptions are sought, could not be legally met due to FDA's actions in response to the COVID-19 PHE. Therefore, the requested exemption will not endanger life or property, or the common defense and security, and is otherwise in the public interest.

Based on the above findings, the NRC grants the following exemption for the specified period of time:

- The deadline for submission of a DFP required by 10 CFR 30.35(e)(2) may be delayed until 90 days from the date of this letter.
- The deadline for submission of a revised Statement of Intent required by 10 CFR 30.35(f) may be delayed until 90 days from the date of this letter.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(G).

If you have questions, please contact Steven Courtemanche of my staff at Steven.Courtemanche@nrc.gov or 610-337-5075.

Sincerely,

Christopher G. Cahill

Digitally signed by Christopher G. Cahill
Date: 2020.04.23 09:16:27 -04'00'

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

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cc: Elon M. Malkin, Radiation Safety Officer

TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 CODE OF FEDERAL REGULATIONS PART 10 CFR 30.35(e)(2) and 30.35(f), DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, MAIL CONTROL NO. 618552 DATED APRIL 23, 2020

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