From: Struckmeyer, Richard
To: Jack Buddenbaum
Subject: Resubmittal RAI

**Date:** Wednesday, April 15, 2020 4:05:00 PM

Mr. Buddenbaum,

The only unresolved item is the following:

10 CFR 40.52(b)(4) requires the applicant to submit the proposed method of labeling
or marking each unit, and/or its container with the identification of the manufacturer or
initial transferor of the product and the source material in the product. Please provide
copies of the labels that will be used on each type of product (or container where the
product is too small to be labeled) that contains thorium.

Note that the regulation states "and/or" and the guidance in NUREG-1556, Volume 8, Revision 1, indicates that for all products to be distributed for use under 10 CFR 40.13(c), the applicant must submit information on labeling to identify the manufacturer or distributor and the type of source material ... Many of the products covered by the exemptions are not practical to label, so it is possible that in some cases only the packaging would be labeled. ... For some products, the initial recipient would need some information about the identity and quantity or concentration of source material. In such cases, packaging or accompanying paperwork would provide the information. In most cases, the identification of the manufacturer or distributor and the fact that thorium or uranium is present should appear on point-of-sale packaging. (See page 9-42)

Note also that it should not be necessary to alter your existing labels; in lieu of this you could add a label for thorium.

Thank you,

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