

From: [Struckmeyer, Richard](#)
To: [Jack Buddenbaum](#)
Cc: "[Hallock, Barry -HEN \(GE, Appl & Light\) \(barryh.hallock@ge.com\)](#)"; [Selmar Dorsey](#)
Subject: RE: Current Lighting Solutions LLC Responses to RAI
Date: Friday, January 10, 2020 3:40:00 PM

Mr. Buddenbaum:

I have reviewed your responses to our RAI, and have additional questions as follows:

1. In your response to Question 7 in our Request for Additional Information, you described the design standards for your lamps and stated that all manufacturing locations are ISO 9001 certified. However, 10 CFR 40.52(b)(3) requires the applicant submit quality control procedures to be followed in the fabrication of production lots of the product.
 - Please submit quality control procedures for manufacturing your lamps. The QC procedure(s) would reference the design standards.
2. In your response to Question 8, you stated that “GE and Current are not aware that our competitors/other suppliers include ‘thorium’ in their labels.”
 - Please provide additional information as to which competitors or suppliers may be distributing or supplying lamps containing thorium and are not including information on their labels regarding the presence of radioactive thorium.
3. In your response to Question 8, you further stated that “GE will have to arrange to have ‘thorium’ added to the marking/labeling for applicable lamps unless the NRC is willing to agree that the Kr-85 marking and product cycle instruction that is provided to general licensees (refer to Attachment 2) is acceptable and ensures adequate product safety.”
 - Please define “product cycle instruction” and describe how this term is relevant to the issue of labeling.
 - Please provide additional information to clarify what is meant by your reference to “general licensees” in this context. Attachment 2 does not contain any mention of general licensees.
4. In your response to Question 8, you further stated that “Product cycle instruction for lamps with Kr-85 are considered adequate for the lamp products that contain unimportant quantities of thorium.”
 - The regulation in 10 CFR 40.52(b)(4) states that the applicant must 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.” 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)

Thank you,

Richard K. Struckmeyer
Materials Safety Licensing and Tribal Liaison Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
301-415-5477

From: Jack Buddenbaum <jack.buddenbaum@plexsci.com>
Sent: Monday, January 06, 2020 12:19 PM
To: Struckmeyer, Richard <Richard.Struckmeyer@nrc.gov>
Cc: 'Hallock, Barry -HEN (GE, Appl & Light) (barryh.hallock@ge.com)' <barryh.hallock@ge.com>; Selmar Dorsey <Selmar.Dorsey@gecurrent.com>
Subject: [External_Sender] Current Lighting Solutions LLC Responses to RAI

Dear Mr. Struckmeyer,
Pleaser refer to USNRC Mail Control Number 616865 and Current Lighting Solutions, LLC responses to your RAIs dated 11-14-19.
Have a good day,

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