



13 January 2014

Maria del Mar Arribas-Colón
Project Manager
U.S. Nuclear Regulatory Commission
FSME/MSSA/LB
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11545 Rockville Pike
Rockville, MD 20852

via UPS and eMail maria.arribas-colon@nrc.gov

Dear Ms. Arribas-Colón;

Please find the additional information as requested in your RAI dated 17 December 2013.

1. Attached is copy of the labels in compliance with the applicable regulations for devices under 10 CFR 31.5 and 10 CFR 31.7. <<2013 attachment label.pdf>>
2. Attached is a copy of our ISO-9001:2008 Certification. <<ISOLITE 111026 Cert ISO 9001 2008 12 13-09 14 – elec.pdf>>
3. Per ISO, we refer to our Quality Assurance and Quality Control program as "QMS" (Quality Management System). The Isolite QMS (previously provided) includes, but is not limited to:
 - Product Realization, which ensures design conformity, including materials, dimensions and tolerances, manufacturing/production methods, assembly methods and part marking.
 - All units are tested in accordance with ANSI/HPS N43.4, Classification of Radioactive Self-Luminous Light Sources. Per NUREG 1556 vol 3 r1 and our SSDR application, no leak test is required. However, the manufacturer (SRBT) does leak test GTLS tubes to a 50 nCi limit per the prototype test requirement in ANSI N43.3.
 - All units are tested for design and performance
 - All units are verified that radiation levels do not exceed the values provided in 10 CFR 71.4 and 71.87
4. Isolite has evaluated the foreign manufacturer's QMS to ensure compliance with the Isolite QMS and regulatory requirements. Isolite has a procedure for Supplier Approval and Re-approval (previously provided). Isolite will require acceptance of its terms and conditions which require compliance with all applicable customer, regulatory, statutory, and AS9100 or ISO9001 and those requirements must flow-down to sub-tier suppliers. Isolite will conduct regular and periodic audits of the foreign manufacturer, per NUREG 1556 vol 3 r1. All of these processes and procedures are documented and maintained in accordance with the Isolite QMS.

Thank you for your assistance with this process.

A handwritten signature in black ink, appearing to read "Bill Rowan", with a stylized flourish at the end.

Bill Rowan

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