Miller, Debra

From: Bill Rowan <browan@isolite.com>
Sent: Monday, January 13, 2014 5:33 PM
To: Arribas-Colon, Maria
Cc: Herrera, Tomas; Jankovich, John
Subject: RE: Request for Additional Information RE: Isolite letter dated September 19, 2013
Attachments: 2013 attachment label.pdf; ISOLITE 111026 Cert ISO 9001 2008 12 13-09 14 - elec.pdf

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.

I have also sent this information in hardcopy via UPS to USNRC at MailStop T8-E24.

Thank you for your assistance with this process.

Bill Rowan
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From: Arribas-Colon, Maria [mailto:Maria.Arribas-Colon@nrc.gov]
Sent: Tuesday, December 17, 2013 2:33 PM
To: Bill Rowan
Cc: Herrera, Tomas; Jankovich, John
Subject: Request for Additional Information RE: Isolite letter dated September 19, 2013

Mr. Rowan -

As requested in letter dated September 19, 2013, we are currently amending Registration Certificate No. NR-1286-D-101-G to add a new manufacturer. In order to complete our review, we will need additional information. Please address the questions listed below:

1. Please provide a final electronic copy of the labels in compliance with the applicable regulations for devices under 10 CFR 31.5 and 10 CFR 31.7.

2. Please provide a copy of your ISO-9001-2008 certification.

3. In your amendment request dated September 19, 2013, you stated that since the original SSDR was granted, Isolite has become ISO-9001-2008 certified and that you have performed a GAP analysis between NRC's QA requirements and ISP and incorporated the additional NRC requirements into your Quality Management Program. Please note that as part of the QA program, in accordance with guidance in NUREG-1556, Volume 3, Revision 1, Section 10.7, "Quality Assurance and Quality Control," your QA program shall include the points listed below. Please confirm that your QA program includes the following:

   - There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling).

   - All units are leak tested to 185 Bq (0.005 µCi).

   - All units are tested for proper operation of all safety features.

   - All units are verified that the radiation levels do not exceed the maximum values stated in the application.

4. Please note that, because in this case Isolite Corporation has affiliation with a foreign manufacturers, it is Isolite Corporation responsibility to assess the manufacturer QA/QC program performance in accordance with your established procedures, accepted standards, or guides. Isolite Corporation must have an established program for assessing the manufacturer's QA/QC program. This includes an evaluation of the foreign manufacturer's performance in accordance with these standards at a frequency necessary to assure that quality requirements are met. Isolite Corporation also must maintain records of such audits for future regulatory review. Please describe how Isolite Corporation will evaluate and audit the manufacturing processes in Canada.

Please submit the requested information within 30 days of the date of this email.

Thank you,

María del Mar Arribas-Colón, M.S.

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