

From: Herrera, Tomas
Sent: Wednesday, February 02, 2011 1:39 PM
To: Jerry Szpak
Cc: Jankovich, John; Struckmeyer, Richard
Subject: Request for Additional Information - Met One Instruments

Mr. Szpak,

I have completed the review of your December 15, 2010, letter responding to the NRC's request for additional information dated November 29, 2010. After reviewing the information you submitted we find that we require additional information in order to complete our review for the renewal of your license.

1. In your December 15th letter you indicated that the Met One Instruments Quality Manual has been Superseded by Appendix E, Updated Quality Manual. The updated quality manual indicates that Met One Instruments is ISO 9001:2008 certified.

NUREG-1556, Vol. 3, Section 10.7 states that the NRC may accept a certificate accreditation in lieu of a full set of QA/QC plans or procedures.

Please provide a copy of Met One's ISO 9001:2008 certificate of accreditation along with a commitment that Met One's QA/QC 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), using sampling methods that meet the provisions of 10 CFR 32.110 or equivalent.
- All units are leak tested to 185 Bq (0.005 μ Ci).
- 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.

Alternatively Met One may provide its full set of QA/QC plans or Procedures

2. In your December 15th letter you stated that point-of-sale package label had been superseded by Form F90003 in Appendix O. Please note that the example of the label indicates that the E-BAM and BAM-1030 contain 60 μ Ci of activity. This quantity is the nominal quantity, the devices can have a maximum activity of 75 μ Ci.

Please provide a revised copy of the point-of-sale package label indicating a maximum activity of 75 μ Ci.

In regards to the BAM-1020, there was no reference to a point-of-sale package label. Please confirm that the same label with the corrected maximum activity information will be used for the BAM-1020.

Please feel free to contact me if you have any questions.

Thank You,
Tomas Herrera
U.S.NRC
FSME/MSSA/Licensing Branch
301-415-7138