UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 3, 2015

Metso Automation USA, Inc.
ATTN: Mr. Jack Ramsey
Sr. Radiation Officer
2425 Commerce Avenue, Suite 100
Duluth, GA 30096

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, METSO AUTOMATION USA, INC., AMENDMENT REQUEST DATED JANUARY 15, 2015

Dear Mr. Ramsey:

This letter is in response to your letter dated January 15, 2015, notifying the NRC of the formation of a new corporation. In reviewing your application, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary.

Please submit the requested information within 30 calendar days of the date of this letter. If we have not received complete information within 30 days, we will consider your amendment request as having been abandoned by you. This is without prejudice to the submission of a complete new amendment request.

If you have any questions, please contact me at Tomas.Herrera@nrc.gov or (301) 415-7138.

Sincerely,

/RA/

Tomas Herrera, Team Leader
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

March 3, 2015

Metso Automation USA, Inc.
ATTN: Mr. Jack Ramsey
Sr. Radiation Officer
2425 Commerce Avenue, Suite 100
Duluth, GA 30096

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, METSO AUTOMATION USA, INC., AMENDMENT REQUEST DATED JANUARY 15, 2015

Dear Mr. Ramsey:

This letter is in response to your letter dated January 15, 2015, notifying the NRC of the formation of a new corporation. In reviewing your application, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary.

Please submit the requested information within 30 calendar days of the date of this letter. If we have not received complete information within 30 days, we will consider your amendment request as having been abandoned by you. This is without prejudice to the submission of a complete new amendment request.

If you have any questions, please contact me at Tomas.Herrera@nrc.gov or (301) 415-7138.

Sincerely,
/RA/
Tomas Herrera, Team Leader
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

Distribution: Case 15-18
Certified Mail Tracking Number: 7014 0510 0000 4426 4349

ML15044A139 (RAI)

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Tomas Herrera	Lymari Sepulveda	Hipolito Gonzalez	Tomas Herrera
DATE	02/18/2015	03/02/2015	03/02/2015	03/03/2015

OFFICIAL RECORD COPY

Metso Automation USA, Inc. Amendment Request dated January 15, 2015
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Metso Automation USA, Inc. amendment request dated January 15, 2015, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556 Volume 3 titled "Applications for Sealed Source and Device Evaluation and Registration."

General

1. Based on Metso Automation USA, Inc.'s letter dated June 16, 2014, to inactivate several Sealed Source and Device registration certificates, please confirm that the following certificates should remain active:
    - NR-0596-D-110-G
    - NR-0596-D-113-G
    - NR-0596-D-114-G

    If any additional registration certificates should be inactivated, please provide the information in NUREG-1556, Volume 3, Revision 1, Section 13.4 "Transfers to Inactive Status".

2. Confirm that the manufacturer and address is the same for all three device registration certificates.

3. On page 1 of your application, you provided the recent serial numbers distributed by the old company for each of the your most recent device models. These serial numbers only pertain to some of the device models that are registered under NR-0596-D-113-G. Please provide the serial numbers for the models BWM2-T, ASM2, BWM, BWM-H, and BWM-L that were distributed most recently. In addition, provide the serial numbers for the last distributed models for those device models that are registered under NR-0596-D-110-G and NR-0596-D-114-G distributed

Labeling

4. On page 2 of your application, you stated that "[t]he only change will be the name of the distributor, and that will be reflected in the distribution and transportation documents."

    Please provide an updated copy of the label containing the information for generally licensed devices that reflects the new name of the distributor "Metso Process Automation USA, LLC," as well referencing the Duluth, Georgia location.

5. Please describe how the labels will be attached to the devices, the materials the labels will be made of, and the dimensions of the labels.

6. Please identify where the lables will be located on the devices registered under NR-0596-D-110-G and NR-0596-D-114-G.

Quality Assurance

7. The quality assurance sections in the three active Metso Automation USA, Inc. registration certificates vary. In an effort to ensure consistency across the certificates please confirm the following:

    i. That the Metso Automation USA, Inc. Quality Assurance program ensures that (1) the materials of construction and the final assembly meet the design specifications, (2) the final product is leak tested, (3) a final radiation profile is performed, (4) a test is performed that verifies that the product operates as intended, including all safety functions, and (5) a visual inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.

    ii. That Mesto Automation USA, Inc. will maintain records in the U.S. as required by the provisions set forth10 CFR 110.53(b), for future regulatory review.

    iii. In accordance with the guidance in NUREG-1556, Volume 3, Revision 1, Section 10.7 “Quality Assurance and Quality Control,” please confirm that Metso Automation USA, Inc. evaluates Metso Automation’s Quality Assurance program in Finland. Please confirm that Metso Automation USA performs periodic audits of facility in Finland.

Safety Analysis

8. The registration certificates as drafted by the State of Georgia did not include certain statements that have been traditionally included in device registration certificates for generally licensed devices. Please confirm that the following statements are accurate for each of the three registration certificates:

    - The devices can be safely operated by persons not having training in radiological protection.

    - Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.

- Under accident conditions associated with handling, storage and use, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF BODY	rem	Sv
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15	0.15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2.00
Other organs	50	0.50