

UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 6, 2015



STEP Analytics USA, Inc.  
ATTN: Mr. Rolf Meinholtz  
Chemist/Engineering Manager/RSO  
P.O. Box 74  
Colora, MD 21917

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, ENVIRONICS USA, INC.  
TRANSFER OF OWNERSHIP DATED FEBRUARY 20, 2015

Dear Mr. Meinholtz:

This letter is in response to Environics USA, Inc. transfer of ownership letter dated February 20, 2015 and STEP Analytics USA Inc. letter with attachments dated March 19, 2015. In reviewing your request, 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 request.

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 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 (301) 415-6026, or e-mail [Maria.Arribas-Colon@nrc.gov](mailto:Maria.Arribas-Colon@nrc.gov).

Sincerely,

**/RA/**

Maria Arribas-Colon, Project Manager  
Materials Safety Licensing Branch  
Division of Material Safety, States, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: As stated

Mail Control Number: 586144

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Maria Arribas-Colon, Project Manager  
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SSD Cases: 15-21 - **Certified Tracking Number: 7014 0510 0000 4426 4387**

**ML15093A095 - \*See previous concurrence**

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Maria Arribas-Colon*	Tomas Herrera*	Shirley Xu*	Hipolito Gonzalez	Maria Arribas-Colon
DATE	04/03/2015	04/03/2015	04/06/2015	04/06/2015	04/06/2015

**OFFICIAL RECORD COPY**

**Environics USA/STEP Analytics USA Transfer of Ownership Request dated  
February 20, 2015  
Request for Additional Information**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed Environics USA, Inc. transfer of ownership dated February 20, 2015, and STEP Analytics USA, Inc. letter with Attachments dated March 19, 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."

1. Please confirm that you are taking over the distribution activities for the following registered device Models:

Device Model No.	Registration Certificate No.
ChemPro 100 V2	NR-1160-D-101-E
ChemPro 100 V3	
ChemPro FX	
M90	NR-1160-D-102-E
MGD-1	
ENVI System	NR-1160-D-103-E

2. Please confirm that the distribution location for the products will be: 414 Summershade Court, Bel Air MD 21015.
3. Provide the serial number of the last device (of each Model) that was distributed by the Environics USA, Inc. prior to the ownership change.
4. Provide the number of completed devices (by Model) that were transferred to be distributed by the Environics USA, Inc. to STEP Analytics USA, Inc.
5. Please provide the change of ownership information discussing transfer of products, records custody, and servicing arrangements for products previously distributed.
6. Provide the new label for all the devices indicating the STEP Analytics USA, Inc. company name and the effective date of the label change.
7. Confirm that no changes were made to any of the Environics USA, Inc. products since the last amendment of each of the Registration Certificates NR-1160-D-101-E, NR-1160-D-102-E, and NR-1160-D-103-E.
8. Confirm that there are no changes to any of previous commitments made by Environics USA, Inc. to the NRC, for the Registration Certificates NR-1160-D-101-E, NR-1160-D-102-E, and NR-1160-D-103-E.
9. It is our understanding that Environics USA, Inc. distributed products under NR-1160-D-101-E, which were marketed under different names (i.e. ChemPro 100i). Please provide a complete list of the different names the products were distributed under and the differences, if any, between those and the ChemPro 100 V2, ChemPro 100 V3, or ChemPro FX.

Enclosure

10. Several of the documents submitted as part of the transfer of ownership were in draft form. The NRC will only accept final version of the documents, please resubmit the documents in final draft.
11. As part of Step Analytics USA, Inc. application to transfer the ownership of devices that were registered by Environics USA, Inc., Step Analytics USA, Inc. provided a revised User's Manual for the devices registered under NR-1160-D-103-E. Please state whether the User's Manual for the devices registered under NR-1160-D-101-E and NR-1160-D-102 have been revised due to the transfer of ownership of the registration certificates. If the User's Manuals have been revised, due to the transfer, please submit the revised final versions.
12. In Attachment 4 of your letter dated March 19, 2015, you stated that STEP Analytics USA, Inc. is not the primary building location of the STEP industrial systems, at this time STEP Analytics USA, Inc. is operating under STEP GmbH QA/QC plan as a sister company and following their QA systems. In addition, you stated that a specific addendum of the QA/QC plan for STEP Analytics USA, Inc. is being made and will be available once it is reviewed and approved by the QA management at STEP GmbH. STEP GmbH is certified according to ISO 9001:2008. Please note that STEP GmbH it is a foreign manufacturer associated with the U.S. distributor (STEP Analytics USA, Inc.), therefore, it is the responsibility of STEP Analytics USA, Inc. to assess the manufacture's QA/QC program performance in accordance with the established procedures, accepted standards, or guides with all statements and commitments made in the application and in the registration certificate. STEP Analytics USA, Inc. 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 the frequency necessary to assure quality assurance is met.

Please note that copies of all records must be maintained in the U.S. as specified by the provisions of 10 CFR 110.53(b) for future regulatory review. With every lot of the product, the foreign manufacturer must forward, to the U.S. distributor, (a) the leak test results and (b) copies of documents certifying that the QA/QC commitments made in the application have been met. The records must be reviewed and approved by the U.S. distributor before the release of the lot. Other QA/QC records must be forwarded to the U.S. distributor on a periodic basis and must be available upon request in a reasonable time. The U.S. distributor must ensure that all QA/QC functions are performed and its responsible for ensuring that the product is distributed with all statements and commitments made in the application and the registration certificate.

Please provide STEP Analytics USA, Inc. QA/QC Program, that includes the oversight process of STEP GmbH manufacturing process (which must include periodic audits of the foreign manufacturer), and please include statements on how STEP Analytics USA, Inc. QA/QC Program will comply with NRC regulation set forth in 10 CFR 110.53(b).

13. In letter dated March 19, 2015, you did not include any information about your QA/QC Program for the products manufactured by Environics OY in Finland. STEP Analytics USA, Inc. QA/QC Program must also include the oversight of products manufactured by Environics OY in Finland, please provide the STEP Analytics USA, Inc. QA/QC Program that includes these products.