UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

June 29, 2011

Mr. Rolf Meinholtz
Chemist/Engineer/RSO
Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, Maryland 21009

Mail Control No. 574851

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Meinholtz:

This letter is in response to your application dated March 21, 2011, for a sealed source and device registration certificate and amendment to your exempt distribution license number 19-23974-01E for the ENVI Series Industrial Detectors. A review of your application indicated that it lacks required information to complete our safety review and evaluation. We have summarized the issues that need to be addressed in an enclosure to this letter.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

If you have any questions regarding your sealed source and device application, please contact Ms. Lymari Sepulveda at (301) 415-5619. For questions regarding your exempt distribution license, please contact Mr. Richard Struckmeyer at (301) 415-5477. Any correspondence regarding the renewal application should reference the control number specified above.

Sincerely,
/RA/
Richard K. Struckmeyer
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal & State Materials &
Environmental Management Programs
Washington, DC 20555

Docket No. 030-37898
Enclosure: As stated

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DISTRIBUTION: JFoster MMoriarty TKime RJones LFARB Region I/DNMS/LAS MSSA r/f

ML111020421 (pkg.)
ML111801166 (RAI)

OFFICE:	FSME:MSSA:LB	FSME:MSSA:LB	FSME:MSSA:LB	
NAME:	RKStruckmeyer	LSepulveda	JJankovich	
DATE:	06/29/2011	06/29/2011	06/29/2011	

OFFICIAL RECORD COPY

Enclosure

Request for Additional Information for the ENVI Series Industrial Detectors

A. Questions related to the sealed source and device registration certificate application

1. Please provide a final version of the manual for the series. Please note that the information submitted for review should be final and that no further changes will be done.

2. In your application you state that the device has not significantly changed. Please explain that statement. Also, please clearly identify the modifications done to the device model IMS 5000 (i.e. dimension, construction, materials).

3. In your application you stated that the ENVI Series consist of three models: ENVI-Air, ENVI-Pro, and ENVI-Stack. Please provide clarification on how you wish the products to be registered, specifically if you want them to be registered as ENVI series or each model individually.

4. Please provide engineering drawings of the device preferably showing different views of the assembly. Please include dimensions of the device and the ion chamber. The drawings should be legible, and show/identify the components. The drawings in Attachment B and C are not legible and do not meet the provisions of 10 CFR 2.390 to warrant proprietary classification. For guidance on engineering drawings, please refer to NUREG 1556 Vol. 3, Rev. 1, Section 6 “How to file”, page 6-2. If you wish to request proprietary classification for the drawings that you will submit to us, please state in a notarized affidavit, how the drawings meet the provisions of 10 CFR 2.390(b)(4).

5. Please provide an electronic copy of the device drawing suitable for inclusion in the registration certificate.

6. Please provide a drawing of the NEMA 4X, outdoor enclosure, and explain how this will be installed and who will be responsible for the installation of the outdoor enclosure.

7. Please provide a drawing indicating the location of the label within the device. Also include the dimensions and units of the label.

8. Please explain what prototype tests were conducted and provide the results of the tests. If you wish to refer to prototype tests which had been conducted on the Model IMS 5000, under the previous registration NR-8199-D-810-E, please demonstrate how the test results apply to the ENVI-series and to the product distributed by Environics.

B. Questions related to the exempt distribution license application

The information requested in the following paragraphs is required by Title 10, Code of Federal Regulations, Chapter 32. Each paragraph is derived from a section within this chapter.

1. Section 32.26(b)(3) requires the applicant to submit information concerning the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product. Your application provided information concerning the chemical and physical form of the byproduct material, but it did not appear to contain information concerning changes in chemical and physical form that may occur during the useful life of the product. Please provide this information.

2. Section 32.26(b)(4) requires the applicant to submit information concerning the solubility in water and body fluids of the forms of the byproduct material contained in the product. Your application did not appear to contain information concerning the solubility in water and body fluids of the forms of the byproduct material. Please provide this information.

3. Section 32.26(b)(8) requires the applicant to submit information concerning the total quantity of BPM expected to be distributed annually. Your application did not appear to contain information concerning the total quantity of BPM expected to be distributed annually. Please provide this information.

4. Section 32.26(b)(10) requires the applicant to submit information concerning the proposed method of labeling or marking the product and its point of sale package to satisfy the requirements of §32.29(b). Appendix F shows a copy of the “Point of Sale Package Label” on the first page, and another label on the second page. The purpose of the second label was not stated; however, it appears to be the label intended for placement on the device. Please clarify how you will satisfy the requirement of Section 32.26(b)(10). The response to this item may be provided in conjunction with item 7 in Part A of this enclosure.

5. Section 32.26(b)(11) requires the applicant to submit information concerning the procedures for prototype testing (containment, shielding and other safety features) under both normal and severe conditions of handling, storage, use, and disposal of the product. Your application did not appear to contain information concerning the procedures for prototype testing. Please provide this information. The response to this item may be provided in conjunction with item 8 in Part A and item 6 in Part B of this enclosure.

6. Section 32.26(b)(12) requires the applicant to submit information concerning the results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features. Your application did not appear to contain information concerning results of prototype testing. Please provide this information. The response to this item may be provided in conjunction with item 8 in Part A and item 5 in Part B of this enclosure.

7. Section 32.26(b)(15) requires the applicant to submit information concerning the quality control procedures followed in fabrication of production lots of the product and the quality control standards product must meet. Appendix J of your application contained certificates which you describe as ISO 9001 and AQAP 2110 certification; however, your application did not appear to contain information concerning Quality Control procedures as required by Section 32.26(b)(15). Please provide information concerning the quality control procedures followed in fabrication of production lots of the product and the quality control standards product must meet.