

## ENCLOSURE

Please address the following items in your new submittal:

1. It was noted while reviewing all of your submitted letters, that there are discrepancies between the submitted materials, particularly that the application version dated May 7, 2001, submitted under cover letter dated May 11, 2001, does not match the redline/strikeout comparison dated March 31, 2001, submitted under cover letter August 15, 2001. During our phone conversation with you on September 4, 2001, you indicated that it was unclear which version was correct, and that you would review the information and submit a copy of the correct version for our continued review. Please submit the correct version as indicated. In addition, please review all information submitted under cover letters dated May 11, 2001, July 23, 2001, August 15, 2001, and August 20, 2001, and either verify that the information contained in the letter is correct, or state that the letter is to be disregarded and provide corrected information as appropriate.
2. The Summary Data in your application dated March 31, 2001, refers to the model number as "M90 Chemical Detector unit with the Ion Mobility Sensor Unit." The model is referred to in the bodies of your response letters as the "M90". We propose to issue the registration certificate under the model number "M90." If this is not acceptable, please indicate the exact model number that you want listed on the registration certificate.
3. Please explain the second sentence in item 2 of your August 15, 2001, letter. What do you mean by your statement "the detector never was distributed as a device"?

## DESIGN

4. Please clarify the radioactive source model to be used in the Model M90. In your cover letter dated August 15, 2001, the source is AMM 1001 and unchanged from the source previously specified. In the distribution license application dated August 26, 1994, it was AMM 1001H. Please specify exact model and holder type for M90 source, and provide the registration number of the certificate the source is registered on. The current registration certificate no. MA-1059-S-174-S, which supersedes IL-136-S-174-S, has four different types source holders for AMM.1001H (e.g., X0849, X0869, X0724, X268/1, X268/2, and X268/3) and two types (Type 1 and Type 2) for AMM.1001. Please indicate the type, and if the AMM 1001H is used, please indicate the source holder.
5. In our previous letter, we requested that you provide complete engineering drawings for the sensor unit module and module components, and basic assembly and component drawings of the complete product. The drawings that you provided in your response are not sufficient. Please send the requested drawings. Note that these drawings must contain materials, dimensions, tolerances, assembly methods, and any other information critical to the design of the device that is not described elsewhere in your application. Drawings that show part numbers must be accompanied by parts lists.
6. The drawings you have submitted in your application have confidential notice. Please provide a waiver regarding the proprietary nature of these drawings or, if you wish to maintain the proprietary classification, 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 2.790. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. For each document or page, please submit two copies. One copy should be an unmarked copy containing all information. The second copy should have removed from it, all information that you wish to be held proprietary. This second copy will be placed in the NRC's public document room. While it is allowable, please refrain from submitting proprietary information in support of a registration unless necessary. Keep in mind that all registration certificates in the Sealed Source and Device Registry, and all NRC licenses are considered to be in the public domain, and are therefore may be viewed by any member of the public who requests to see them.

7. It is our understanding that the high security Torx fasteners that you will use are the style that contain a pin centered in Torx opening. Please confirm this. Please indicate the material used for the Torx screws. Please list the location of all tamper-resistant fasteners. Bear in mind that the design of the product must be such that the radioactive material is not separable from the device, even during maintenance of non-radioactive components and cleaning.
8. It was noted that your May 7, 2001, version of the application indicated use of an "internally mounted sampling pump." Your March 31, 2001, redline/strikeout version of the application and the original application from the expired license indicated use of an "externally mounted sampling pump." Please verify that the device uses the "externally mounted sampling pump" as per the original design, or provide corrected information. If a change has been made to an internal pump, please address this change as it affects the prototype testing of the product.

#### PROTOTYPE TESTING

9. Earlier prototype testing indicates that the Sensor Unit was tested within a detector device; however, the information on file does not list the device used. Please indicate whether this was the current M90, with no changes in design from the model tested. If there have been any changes to the M90 from the testing unit, or if another device was used in the testing, please provide full prototype testing information that addresses the integrity of the complete product. This may either be testing of the M90 as a complete product, or testing of the Sensor Unit combined with engineering analysis that demonstrates that the Sensor Unit will not be damaged by any components of, or within, the M90 during the same tests.

#### LABELING

10. Please indicate the location of the label on the sensor unit.
11. Please provide the technical specifications for self-adhesive Lexan film used for the sensor unit labeling as indicated in your August 15, 2001, letter, and demonstrate that the label will survive the expected use conditions, including remaining legible, over the lifetime of the product. If the label will require replacement during the lifetime of the

product, please provide a copy of the instructions to the user for inspecting and replacing the label.

12. Please indicate the material used for the detector label, and demonstrate that the label will survive the expected use conditions, including remaining legible, over the lifetime of the product. If the label will require replacement during the lifetime of the product, please provide a copy of the instructions to the user for inspecting and replacing the label.
13. Please describe the point-of-sale packaging for the product and indicate the location of the labeling required by 10 CFR 32.29(b)(3).
14. Please indicate the material used for the POS label, and demonstrate that the label will survive the expected shipping conditions, including remaining legible and intact.
15. Your 8/15/01 letter illustrates the label on the sensor unit. The label lists Environics Oy in Finland. For units distributed in the US, it is suggested that SAI contact information and SAI's license number should be listed, either as additional information on the label or on a separate label, so that US users will have a US contact in case of problems or questions in the event that the module becomes separated from the device. Please provide updated information if you wish to add the information, and indicate the location of this information on the sensor module.
16. Your 8/15/01 letter illustrates the label on the device and the point-of-sale package. The label lists SAI as the initial distributor as appropriate. It is suggested SAI use their license number instead of the company name to meet the requirements in 10 CFR 32.29(b)(1)(iii) and 32.29(b)(3)(ii). This will preclude the necessity to change the label commitments in the event of any future company name change. Please provide updated information if you wish to change the information.

#### QA/QC

17. Please confirm that your QA/QC programs meet the RG 6.9 criteria, particularly Appendix C. If you need RG 6.9, it is available through NRC website ([www.nrc.gov/NRC/RG/06/09-009.html](http://www.nrc.gov/NRC/RG/06/09-009.html)).
18. In Section E, "Quality Control," the last paragraph stated that "All records of these test will be maintained at Temet in the United States." Your August 15, 2001, letter informs us that Temet changed its name to Sensor Applications. Please update the statement to reference the new company name of Sensor Applications.
19. Please provide a copy of the ISO 9001 certificate, if Environics, Oy has been certified.
20. Please provide a copy of Drawing Numbers 1 through 4 specified in Section E, "Quality Control," which are apparently missing from your application.
21. Please provide the English version of Follow-Up Card (Environics Document No. 1094-04680M).

22. Please provide Drawings depicting a typical installation stated in Section G, "Installation," which are apparently missing from your application.

September 13, 2001

Sensor Applications Inc.  
Attn: Mr. Kenneth Burbach  
737 Walker Road, Suite 1  
P.O. Box 439  
Great Falls, VA 22066-2833

SUBJECT: LICENSE APPLICATION FOR DISTRIBUTION OF MODEL M90

Dear Mr. Burbach:

This refers to your application dated May 11, 2001, and subsequent correspondence, requesting a license to distribute the M90 detector to exempt persons, as previously authorized by expired License No. 45-25316-02E. We discussed your application on several occasions by telephone with Mr. Richard Krahe, Mr. Eli Port, and yourself, most recently during the period September 4-11, 2001.

As discussed previously, we have issued you a new license, which provides a temporary authorization to resume distribution of the M90 under conditions similar to the expired license, for the period September 11, 2001, through January 31, 2002. This license was faxed and mailed to you in separate correspondence.

In order for us to complete our review related to authorizing distribution after January 31, 2002, you will need to provide additional information, as discussed below:

1. As discussed with Mr. Port, there are conflicts and discrepancies between your May 11, 2001, and August 15, 2001, submittals. You need to provide a complete, accurate submittal which reconciles and supersedes the previous submittals dated May 11, July 23, August 15, and August 20, 2001. It would also be helpful to include a "redline/strikeout" version which identifies differences from your 1995 application.
2. You need to submit engineering drawings of the M90 device in English.
3. In preparing the submittal, you need to consider and address the items identified in the Enclosure. These items are mostly based on our review of your August 15, 2001, submittal. Please note that additional information may be required when we complete our evaluation.

If you have any questions, please contact Mr. Seung Lee at (301) 415-5787 or Ms. Michele Burgess at (301) 415-5868.

Sincerely,

*/RA/*

John W. Hickey, Chief  
Materials Safety and Inspection Branch  
Division of Industrial and  
Medical Nuclear Safety

Enclosure: As stated

cc: Mr. Eli Port, RSSI

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