July 28,2000

Richard R. Thomas, President
Environmental Technologies Group, Inc.
1400 Taylor Avenue, P.O. Box 9840
Baltimore, Maryland 21284-9840

SUBJECT: DISCONTINUED REVIEW OF REQUEST TO REGISTER MODEL APD-2000

Dear Mr. Thomas:

We have completed a review of your application dated March 10, 2000, requesting to register a chemical agent monitoring device, Model APD-2000, with an ion mobility spectrometer cell containing a radioactive source of Ni-63, for distribution to persons exempt from licensing under the provisions of 10 CFR 30.20 and 32.26. In reviewing the application, we found it was lacking significant amounts of the required information. In an Enclosure to our letter dated June 22, 2000, we had summarized the major areas of concern not addressed in your application. To date we have not received a response from you to our letter.

Therefore, we have discontinued the review of your application. This is without prejudice to re-submission of your application. If you decide to re-submit your application for registration and exempt license, please respond to our questions and ensure that you have included sufficient information to allow NRC to evaluate your design.

If you have any questions, please call Mr. Anthony Kirkwood at (301) 415-6140 or Dr. Seung Lee at (301) 415-5787.

Sincerely,

/RA/

John Jankovich, Ph.D., Team Leader
Materials Safety and Inspection Section A
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Enclosure to Letter to Mr. R. Thomas
Request for Additional Information
Application dated March 10, 2000

1. Appendix A of your application lists 20 drawings and text in section 5, pages 5 to 11, that are to be considered proprietary. Please be aware that you may request that certain portions of your submittal to the NRC be withheld from public disclosures as proprietary information. To do this however, you must execute an affidavit as specified in 10 CFR 2.790, which will entail additional review time by our legal staff. You must list all portions you wish to be held as proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a registration unless necessary. You may try submitting the information with the proprietary information deleted. Keep in mind that all registration certificates and all NRC licenses are considered to be in the public domain, and may be viewed by any member of the public who requests to see them.

2. Appendix A, Introduction, on page 1 of your application, indicates that the AP-2000 is currently distributed under agreement license per COMAR C.22(d), Maryland General License provisions as described in Attachment 11. However, your Attachment 12, the Maryland Registry Certificate No. MD-263-D-102-G does not appear to list the Model APD-2000. Please provide the Maryland sealed source and devices (SS&D) registration certificate for the Model APD-2000 or indicate which one on the attached registry is the APD-2000.

3. Your Section 5, page 5, 2nd paragraph, describes Attachment 5 as showing a specialized tool for removing tamper resistant screws, however the attachment shows a label instead. Please submit an attachment showing the specialized tool for removing the tamper resistant screws or indicate that it is shown on the last page of Attachment 9.

4. In Section 5, page 9, of your application you indicated that the sieve pack should be replaced by ETG annually. Please specify the other measures that should be done for maintenance and the required frequencies in regard to such items as the membrane, charcoal filter pack, port filters, and viton tubing. Provide the battery replacement frequency.

5. In Section 13, page 12, change the nominal activity of 10 mCi to the maximum activity of 15 mCi for your groundwater contamination scenario since members of the public could receive doses commensurate with an activity of 15 mCi as indicated on your NRC Form 313, Item 5.b. Therefore, that activity must be used in your hazard evaluation calculations.

6. You provided prototype testing for temperature only. Please provide results of prototype testing that demonstrates the effectiveness of the containment, shielding, and the safety features under both normal and likely accidental conditions of handling, storage, use, transport, and disposal of this product for other factors such as vibration, shock, drop, impact, corrosion, etc. Provide maximum allowable vibration, shock, corrosion, etc. Please provide the tests and procedures used.

7. Discuss the potential for corrosion between unlike metals (e.g., aluminum and steel), consequences of this corrosion, and how the adverse effects of corrosion will be minimized.

8. Quality Control (QC) and Quality Assurances (QA) information provided is not sufficient to adequately evaluate the program. In Section 15.1, you indicated that ETG, Inc., is

ISO 9001 certified. Please provide a copy showing ISO 9001 certification. If you wish to use your ISO-9001 approval as a part of the approval of your QA/QC, then you must: (1) use an acceptable level of removable contamination of <0.005 microcurie (185 Bq), (2) commit to manufacture and distribute all units in accordance with ISO-9001, (3) Provide an inspection procedure to ensure, prior to distribution, that:

a. Correct labeling on the device and inclusion of correct user manual/materials
b. Tamper-resistance hardware is in placed as described in the application
c. All units are leak tested to less than 0.005 microcurie (185 Bq)
d. Device safety features function properly
e. The distributor should audit and document annually that the manufacturer maintains the ISO 9001 qualifications if different then the distributor. Provide a copy of the ISO 9001 certificate of the manufacturer.
f. Sampling methods are used to ensure design conformity and that meet the minimum sampling rates in 10 CFR 32.110. Section 15.2, page 18, of your application, features a chart showing incoming inspection on parts that does not conform to current acceptable NRC statistical sampling procedures as found in Regulatory Guide 6.9 (RG 6.9), "Establishing Quality Assurance Programs For The Manufacturing And Distribution Of Sealed Sources And Devices Containing Byproduct Material." For example, the sampling table found in RG 6.9, Appendix C, page C-6, for LTPD = 5%, does not allow any lots with any rejects and larger sample sizes than found in your table would be required in lot sizes ranging from 1-150 (see RG 6.9 enclosed).
g. Your Quality Assurance Plan reflects any maintenance, repair or replacement activities. Will these activities be handled in the same fashion as for a new unit?

10. Your Attachment 7, contains Receiving Inspection Instructions that indicate a sampling level on sources received. However, this conflicts with your statement in Section 15.2, page 17, that indicates inspection on a 100% basis. Please explain this conflict.

11. It appears from the information you submitted, that a long thin object, such as a pencil, could be inserted into the device and damage the membrane. From this we conclude that a containment barrier can be breached and thus allow radioactive material, leaking from the nickel-63 source, to contaminate members of the public. Describe how your device prevents this or how you will modify your device design to prevent this from happening.

12. Please state how your model numbering system will differentiate the APD-2000 devices from a generally licensed device.

13. The nickel-63 source drawing, Attachment 2, page 29, was partially cut-off. Please resubmit this drawing in its entirety.

14. We cannot locate Drawing No. 2428630 and Sheet 1 of 2 for Drawing No. PL2429249. Please submit copies of these drawings.