September 5, 1996

Al McEachern
CPAD Technologies Inc.
66 Slater Street
Ottawa, Ontario
Canada
K1P 5H1

Dear Mr. McEachern:

This concerns information about an Ion Mobility Spectrometer (IMS) Detector which was submitted with your facsimile received September 4, 1996, in response to the deficiency letter dated August 27. I have performed a cursory review of the information and have identified areas where additional information or clarification is needed.

1. Your request for an exempt distribution license has not been received. If this has not been submitted yet, it is recommended that you do so as soon as possible.

2. With respect to the environmental and operating extremes the device may experience, you state that the device will be used for exterior operations. Does this mean the device is portable or moveable, or will it be installed in a fixed position outside, open to the environment?

3. The labels on the analytical unit you state will be expected to remain intact on the device at temperatures up to 100 degrees C. What is the maximum temperature of the surface the label is attached to will reach?

4. Per our conversation on September 3, you stated that the label on the detector will have the information engraved in the aluminum. Your letter did not address this. Please verify how the information will be applied to the label.

5. What material will be used for the label attached to the analytical unit? In addition, what adhesive will be used to attach this label to the analytical unit?

6. With respect to the quality assurance program, please provide a description of the quality control program that is used for the manufacture of the IMS Detector. Please note that your quality control program must ensure that devices meet all specifications provided in your application. Please address how this will be accomplished as well as leak testing of the devices. Coulter Sales will have to do a visual inspection to ensure that devices meet all specifications provided in your application and perform a leak test of all devices shipped or if this is performed by CPAD Technologies Inc., Coulter Sales will have to perform periodic audits to ensure CPAD Technologies Inc. maintains an adequate quality control program.

7. Please provide scenarios and dose assessments in accordance with 10 CFR 32.27.

8. Please explain the tamper proof screws and their locations on the device.

Sincerely,

Brian W. Smith, Health Physicist
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards