UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 27, 1996

Mr. Al McEachern, Director
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 letter received July 10, 1996, and your subsequent conversation with Ms. Kathleen Dolce of Region I. We are in the process of reviewing the information and have identified areas where additional information or clarification is needed. As requested in your conversation with Ms. Dolce, the information was reviewed for distribution of the devices under an exempt distribution license under 10 CFR 32.26. As per 10 CFR 32.26, these devices will be used by persons defined in 10 CFR 30.20. It is our understanding that a letter will be submitted explaining this change. Because 10 CFR 32.26 contains different requirements than 10 CFR 32.51, which your original submittal requested the devices to be distributed under, additional information will be necessary and some changes will be required to be made to the information originally submitted.

Devices manufactured under 10 CFR 32.26 must be designed for the purpose of protecting life or property from fires and airborne hazards. Accordingly, a case will need to be made for the IMS Detector to be manufactured under use 10 CFR 32.26.

It was noted in the engineering drawings submitted that a statement was made on each that it is considered to be the property of CPAD Technologies Inc. The NRC can handle information submitted by licensees on a company proprietary manner (i.e., not to be disclosed to the public) when the materials are submitted in accordance with 10 CFR 2.790(b). In addition to the markings on the material to be considered proprietary, an affidavit is required to be submitted requesting that the materials be considered proprietary. Once this has been received, the NRC will consider the request on its merits.

To aid in the development of this additional information, I have enclosed a copy of "Supplemental Information to Request a Safety Evaluation and Registration of Sealed Sources or Devices Containing Byproduct Material" which contains all of the regulations relevant to your submittal. Because of this, some of the following questions will only reference sections of the regulations instead of including the regulation text. In addition, I am including a copy of Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," which provides guidance on submitting requests to the U.S. NRC for radiation safety evaluation and registration of devices containing byproduct material.

In order to complete our review, please provide the following:

1. With respect to the model number scheme that is proposed to be used, we recommend that you include IMS as a prefix (i.e., IMS-xxxx-yyyy). In your application, the "xxxx" represents the model number. Please explain the meaning of different model numbers, if used.

2. Devices distributed under 10 CFR 32.26 do not require leak testing by their users.

3. Please provide the extremes of environmental and operating conditions (e.g., temperature, humidity, corrosive atmosphere, vibration, etc.) the device may experience during normal use. In addition, please provide a brief description of the function and operation of the device.

4. Please provide the expected useful life of the device.

5. Please provide the total quantity of byproduct material expected to be distributed in the product annually.

6. Devices distributed under 10 CFR 32.26 must be labeled in accordance with 10 CFR 32.29(b). The following requests for information all pertain to labeling.

   - A label must be placed on the detector that contains the following: (1) the words "Contains Radioactive Material," (2) the name of the radionuclide and quantity of activity, and (3) the identity of the 10 CFR 32.26 licensee. The label must be durable, legible, and readily visible when the detector is removed from the analytical unit (box that contains the IMS detector). Please provide the wording or samples of the label to be placed on the detector.

   - In addition to the label that will be placed on the detector itself, a label must be placed on the outside of the analytical unit. This label must contain, as a minimum, the same information as that required to be on the detector. Additional information may be included.

   - These labels need to be permanently affixed to the device and made of a material that will retain its integrity during use. Please indicate the materials of construction of the labels. In addition, please provide information on the label adhesive, such as solubility, effective temperature range, etc.

   - In addition to these labels, the point of sale package must be labeled or marked in accordance with 10 CFR 32.29(b)(3). This label or marking must contain the following: (1) the name of the radionuclide and quantity of activity, (2) the identity of the 10 CFR 32.26 licensee, and (3) the following or similar words "This detector contains radioactive material and has been manufactured in compliance with U.S. NRC safety criteria in 10 CFR 32.27. The purchaser is exempt from any regulatory requirements." The label or marking must be legible and readily visible on the package. Please provide the wording or samples of the label or marking to be placed on the point of sale package.

7. With respect to prototype testing, please provide details on the condition of the devices tested when each test was completed (i.e., did the device fall apart, any visible damage, condition of source, etc.).

8. Please provide complete radiation profiles for the IMS Detector assembly and the analytical unit containing the maximum activity for the source. Indicate whether the radiation profiles are derived from calculation or from surveying the device. If they are derived from surveying the device, please provide a description of the instruments used to perform the surveys. The radiation profiles must be provided at 5 and 25 centimeters from the external surface of the detector. These measurements must be made with the detector inside and outside of the analytical unit.

9. 10 CFR 32.29 (a) requires that adequate quality control procedures be carried out to assure that each production lot meet the quality control standards approved by the NRC. 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. Materials that do not meet the minimum specifications will not be authorized under the certificate.

10. Dose assessments must be provided that demonstrate that the device meets the safety criteria in 10 CFR 32.27. (i.e., certain dose limits under normal use and disposal conditions). Therefore, please review these requirements (see enclosure) and submit sufficient information to prove that the safety criteria can be met.

11. With respect to the degree of access to human beings to the product during normal handling and use, the device should have safety features in place to prevent the inadvertent access to the source by the user. Please provide a description of the safety features of the IMS Detector. Typical safety features include tamper resistant screws, use of adhesives, and filled screw heads.

12. Please address the potential for galvanic corrosion of the device, in particular the locations where different materials come into contact.

13. For each engineering drawing provided in your application, please provide a parts list including the materials of construction.

14. The registration certificate for the Nuclear Radiation Developments, Inc. source model number N-1001 states that the source can be made with one of several backing foils. Please provide the backing foil used for the sources to be used in the IMS Detector.

We look forward to receiving the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5723 or Mr. John Lubinski at (301) 415-7868.

Sincerely,

Original Signed by

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

Enclosures: As stated

cc: Mr. Gordon Coulter, Coulter Sales
Ms. Kathleen Dolce, Region I

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OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY

FAX TRANSMITTAL

TO	LOCATION
1. Al McEachern	CPA Technologies Inc.
FAX # (613) 230-3805	VERIFICATION ( )
2.	
FAX # ( )	VERIFICATION ( )
3.	
FAX # ( )	VERIFICATION ( )
4.	
FAX # ( )	VERIFICATION ( )

COMMENTS.

COVER SHEET PLUS 4 PAGES

FROM: Brian Smith

PHONE: (301) 415-5723

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Brian W. Smith, Health Physicist
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cc: Mr. Gordon Coulter, Coulter Sales
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