From: Brian Smith
To: internet:almc@cpadtech.com
Subject: Deficiency Letter for IMS Detector

This letter contains the questions as discussed in our phone conversation on 10/9/96. The file was saved in Word 6.0 format.

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

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, facsimiles dated September 4 and 23, 1996, and letter dated September 23, 1996. We are in the process of reviewing the information and have identified areas where additional information or clarification is needed. In order to complete our review, please provide the following:

1. The wording for the label to be attached to the analytical unit that was submitted in your facsimile dated September 4, 1996, contains an incorrect statement. The label should be changed to say the device is exempt from regulations. However, a label that contains wording similar to that on the point of sale package would be sufficient also. Please provide the wording for the label to be attached to the analytical unit.

2. The label attached to the device itself and the point of sale package must identify the holder of the registration certificate - Galson Corporation. This can be accomplished by adding Galson Corporation or their license number to the label. Please provide the wording for the labels.

3. The model numbering scheme includes devices that use photo ionization in place of the Ni-63 source. For the devices that utilize photo ionization, it is recommended that this model numbering be modified to avoid any potential for mislabeling.

4. Your quality assurance program should meet the criteria discussed in Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material." Please verify that your program meets these criteria, including Appendix C. This guide is included in this letter as an enclosure. Also included with this guide is an acceptable alternative to the quality control program specifications located on page C-4.

5. 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 and submit sufficient information to prove that the safety criteria can be met. NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," is included with this letter as an enclosure to aid in the development of this additional information.

6. Because the registration certificate will be in the name of Galson Corporation, a letter is needed from Galson Corporation stating that they will abide by all requirements of the Nuclear Regulatory Commission and commitments made by CPAD Technologies in the application for registration of the IMS Detector and any letters submitted to the NRC in response to deficiencies identified during the review of the device.

7. Please verify that the IMS Detector is used as a component in another device for the purpose of detecting explosives only.

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,

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. Michael Howe, Galson Corporation