



October 11, 1996

Mr. Brian W. Smith, Health Physicist
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial Safety
Office of Nuclear Material Safety
and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Smith:

In response to your e-mail of October 10, 1996, I have responded as indicated. the response to paras 4 and 5 will follow.

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.

Reply:

The label affixed to the Analytical Unit will contain the following information:

WARNING--CONTAINS RADIOACTIVE MATERIAL

THIS ANALYTICAL UNIT CONTAINS A DETECTION SYSTEM THAT HAS AS PART OF ITS SYSTEM A "DEVICE" THAT CONTAINS A RADIOACTIVE NICKEL - 63 SOURCE AT 3.3 MILLICURIES. IT HAS BEEN MANUFACTURED BY CPAD TECHNOLOGIES INC. OF OTTAWA CANADA, IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS

9702260208 961230
PDR PR *
SSD PDR

CPAD Technologies Inc.

66 Slater Street, 8th Floor, Ottawa, Ontario, Canada K1P 5H1

Tel.: 613.230.0609 Fax: 613.230.3805
E-mail: cpadtech@cpadtech.com

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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.

Reply:

The label on the device will include **"U.S. LICENSE # 2260-3047"** which is the Galson Corporation license number.

The label on the sale package will include **"THE U.S. POSSESSION LICENSE IS HELD BY GALSON CORPORATION."**

THIS CRATE CONTAINS A DETECTION SYSTEM THAT HAS AS PART OF ITS SYSTEM A "DEVICE" THAT CONTAINS A RADIOACTIVE NICKEL - 63 SOURCE AT 3.3 MILLICURIES. IT HAS BEEN MANUFACTURED BY CPAD TECHNOLOGIES INC. OF OTTAWA CANADA, IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE U.S. POSSESSION LICENSE IS HELD BY GALSON CORPORATION. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

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.

Reply:

The model numbering for an IMS Detector that uses photo ionization will show **PD** (for photo ionization detector) instead of the **PI** as first indicated.

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

Reply:

The information requested will be submitted when the referenced material is received.

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.

Reply:

The information requested will be provided.

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.

Reply:

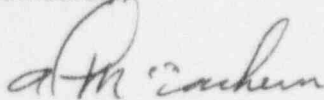
A letter will be sent to Galson Corporation requesting that the Company state that it will abide by all requirements of the Nuclear Regulatory Commission and commitments made by CPAD Technologies Inc. in the application of the IMS Detector including responses to deficiencies identified during the Device review.

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

Reply:

The IMS Detector, containing Ni - 63, is used in the ORION Explosives Detection System, and in the SIRIUS Narcotics and Explosives Detection System, only for the detection of explosives.

Sincerely,



A.L. McEachern
Director, Business Development



October 11, 1996

Mr. Michael L. Howe
Galson Corporation
6601 Kirkville Road
East Syracuse, NY
13057

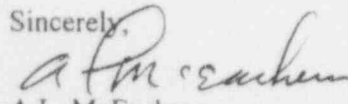
Dear Mr. Howe:

The information you supplied was very helpful, thanks for your quick response. I have just received a reply from the NRC with respect to the "device" review; Mr. Smith sent a copy to you, however it may take a few days to arrive. To complete the information required, the NRC requires a letter signed by the Galson Corporation. The following is a quote from their correspondence:

"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."

Based on your past experience with the NRC, I am sure you are aware of the above requirement. You can be assured that CPAD will provide you with a copy of what we are obligated to do as a result of the device review; the only thing I see for the Galson Corporation to do, is confirm that we are living up to our obligations. If you have any questions on this please do not hesitate to contact me.

Thanks for your support in this matter.

Sincerely,

A.L. McEachern
Director, Business Development

cc: Mr. Brian Smith NRC Headquarters

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE



FACSIMILE

Date & Time: Friday, October 11, 1996 8:55 AM

Pages To Follow: 3

Send To

Name: Brian Smith
Company: NRC Headquarters

FAX: 301-415-5369
Phone: 301-415-5723

From

Name: Al McEachern

Address: CPAD Technologies Inc.
66 Slater Street, 6th Floor
Ottawa, Ontario K1P 5H1

Phone: (613) 230-0609
FAX: (613) 230-3805

cc:

Subject: NRC DEVICE REVIEW

Notes: Further to our conversations on this subject, and your e-mail dated October 10, 1996, this fax contains my response as far as I can go. Your observations on the QA and dose assessments will be actioned when the hard copies of the referenced material is received.

Thanks for your support.

Sincerely,

A handwritten signature in dark ink, appearing to read "A.L. McEachern".

A.L. McEachern
Director, Business Development

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

WARNING!

This CPAD Technologies Inc. transmission is intended for the addressee. It may contain privileged or confidential information, any unauthorized disclosure is strictly prohibited by law. If you have received this transmission in error, please notify us immediately so that we may correct our transmission. Please then destroy the original. Thank you.



October 11, 1996

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CPAD Technologies Inc.

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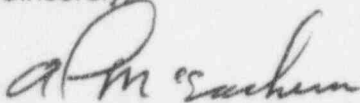
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