



September 17, 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 the letter of Aug 26, 1996, and your conversations with Mr. McEachern, it appears that it is in the best interest of CPAD to request an "Exempt Distribution License". Please void our initial request (mail control number 123410), a new NRC Form 313 will be completed and forwarded to the NRC headquarters as advised.

Thanks for your support in this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "Scott Feagan", written over a horizontal line.

Mr. Scott Feagan
President
CPAD Technologies Inc.

cc: Ms. Kathleen Dolce, Region 1
Ms. Susan Greene, NRC Headquarters

9702270009 961230
PDR RC *
SSD PDR

CPAD Technologies Inc.

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WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE



FACSIMILE

Date & Time: Wednesday, September 04, 1996 10:21 AM **Pages To Follow:** 6

Send To

Name: Mr. Brian Smith
Company: NRC

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

From

Name: Al McEachern

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

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

CC:

Subject: DEVICE REVIEW

Notes: Further to our conversation, this fax contains replies to your observations, except for para 13. I will be reviewing the drawings this afternoon and we will provide the information requested, and at the same time a decision will be made as to what drawings should be protected. When I have the information to reply to para 13, I will put the replies into hard copy with a covering letter.

Company management agrees with the suggestion that we apply for an "Exempt Distribution License".

Thanks for your assistance in this matter.

Regards,

A handwritten signature in cursive script, appearing to read "Al McEachern", written over a horizontal line.

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.

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.

Reply:

The Model Number will be prefixed with "IMS". The Model Number will be a 15 digit number:

- a. The first three digits will be IMS.
- b. The next two digits will be the type i.e. NI (for nickel source) or PI (for photo ionization).
- c. The next digit will be a P (for particle capture and detection (PCAD)) or a V (for vapor capture and detection (VCAD)).
- d. The next three digits will be the voltage i.e. 110 volts, 220 volts or 024 volts.
- e. The next two digits will be the current i.e. AC or DC.
- f. The last four digits will be the number on the IMS.

The Serial Number will be an eight digit number:

- a. The first two digits will be the year of manufacture.
- b. The next three digits will be the day of manufacture (using the Julian date).
- c. The last three digits will be the number produced on a specific day.

An example of a Model Number and a Serial Number for a typical Analytical Unit, using the above would be as follows:

Model: IMSNIP110AC0014 Serial: 96125015

This would be an Analytical Unit that contains an IMS, a Ni-63 source, a PCAD, 110 volts, alternating current, and the number of the IMS is 0014. And it was manufactured in 1996 on the 125th day, and it was the 15th unit produced that day.

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

Reply:

The requirement for leak testing will be removed from our procedures.

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.

Reply:

The Explosives Detection Equipment is designed to operate in an airport type environment, to field conditions where the conditions are those expected for exterior operation. The device, which is enclosed in the equipment experiences a temperature of 260 degrees C. Because the device works in a dry nitrogen atmosphere, humidity and corrosion is not a problem. The samples that are injected into the device are nanogram quantities and are not corrosive. The mounting of the device within the analytical unit is such that vibration is not a problem.

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

Reply:

The device has no moving parts, as such it is not subject to wear out conditions. The life of the device will be determined by time the main equipment becomes obsolete in about five years.

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

Reply:

Each main equipment will contain one or two devices, and to be considered successful in the United States market it is hoped that sales will reach 50 units per year. The estimated quantity of byproduct material distributed annually is 165 to 330 millicuries.

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

Reply:

CPAD will conform to the labeling requirement as to wording, durability, legibility and visibility. The label will be as follows:

**CONTAINS RADIOACTIVE MATERIAL
NICKEL-63 AT 3.3 MILLICURIES
CPAD TECHNOLOGIES INC.
SER #**

The label will be made from aluminum plate 20 thousands thick, and secured to the device with screws or rivets.

- 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.

Reply:

The label affixed to the analytical unit will have the same information as on the device, plus the additional information as depicted on the label:

WARNING--CONTAINS RADIOACTIVE MATERIAL

THIS ANALYTICAL UNIT CONTAINS A SEALED RADIOACTIVE SOURCE: NI 63 AT 3.3 MILLICURIES.
DISASSEMBLY AND REMOVAL OF THE RADIOACTIVE SOURCE MUST NOT BE ATTEMPTED
EXCEPT BY CPAD TECHNOLOGIES INC. THE RECEIPT, POSSESSION, USE AND TRANSFER
OF THIS UNIT MODEL: _____, SERIAL: _____ ARE SUBJECT TO THE REGULATIONS
OF THE U.S. NRC OR THE STATE WITH WHICH THE NRC HAS ENTERED INTO AN
AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. THIS LABEL SHALL BE MAINTAINED
ON THE UNIT IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED

- 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.

Reply:

The label on the analytical unit will be constructed from material that will withstand temperatures in excess of 100 degrees C, and applied with an adhesive material also capable of withstanding the 100 degree C temperature.

- 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.

Reply:

The label affixed to the package will contain the following information:

**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 PURCHASER IS EXEMPT
FROM ANY REGULATORY REQUIREMENTS.**

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

Reply:

When a production model IMS (device) was tested there was no evidence that the device had suffered any damage that would affect its operation. After the drop test the sharp edges were marred where the device struck the steel plate.

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 centimetres from the external surface of the detector. The measurements must be made with the detector inside and outside the analytical unit.

Reply:

The source emits 100% beta at 67 keV, completely surrounded by aluminum with a wall thickness of 2 cm. ; all the beta electrons will be absorbed by the metal, and Ni -63 does not emit electromagnetic radiation (gamma rays).

9. 10 CFR 32.29(a) required that adequate quality control procedures be carried out to assure that each production log 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.

Reply:

The production facility for the manufacture and assembly of the "device", containing the Nickel - 63 is approved by the Atomic Energy Control Board of Canada, (AECB)), and all activities associated with working on radioactive material, from monitoring to waste disposal is governed by AECB regulations. A room within the facility has been earmarked for all work involving radioactive material. Before beginning any work involving radioactive material, the work area is cleaned, and a clean disposal place mat is applied to the work bench. The tools used are only for work on the "device". Once a month the work area is wiped and the sample is sent to an independent lab for analysis. The company is in the process of ISO 9000 qualification/certification.

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 and submit sufficient information to prove that the safety criteria can be met.

Reply:

The device does not emit gamma or alpha radiation, and the Ni - 63 Beta radiation is below thresholds mentioned in 10 CFR 32.28.

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.

Reply:

The system is assembled with tamper proof security screws and production quantities of the IMS will also include tamper resistant screws.

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

Reply:

The "device" is manufactured with aluminum, nickel, and stainless steel, and works in a dry nitrogen atmosphere: galvanic corrosion is not a problem.

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

Reply: **To follow.**

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.

Reply:

The backing foil is made of Nickel.