DETEC

Dose Assessment of the
Ion Mobility Spectrometer
Containing Ni^{63}

prepared by: J. Dubeau

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Summary

The IMS (Ion Mobility Spectrometer) is used in a system to be manufactured in Canada and sold in the US at a predicted rate of 50 units a year. Each IMS unit will contain 3.3 mCi of Ni^{63}, a β emitter with an endpoint energy of 67 keV. Hence, the instrument must comply with US federal regulations, notably table 32.28 of 10CFR32.27 which provides annual dose equivalent limit for various organs for internal and external exposure to the radioactivity. In this work, established Monte Carlo techniques and published fluence to dose conversion coefficients are used to assess the dose risk in a situation of normal use of the IMS and in an accident situation where the source is outside its shielding enclosure. In all situations, under reasonable assumptions, it is demonstrated that the dose limits set by 10CFR32.27 are not exceeded.

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1.0 Introduction

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The annual equivalent dose limits are listed in table 32.28 of 10CFR32.27. It lists 3 categories of radiation exposure in 3 columns. Column I is concerned by the dose to organs caused by the ingestion or inhalation of radioactive material. Column II give dose limits which are unlikely to be exceeded. We view these as representing dose limits during the normal operation of the IMS. In column III, very high dose limits are given for which there is a negligible risk of exceeding. We view these as dose limits for accident situations. Dose limits in all 3 columns are specified according to exposure to the extremities, the whole body and other organs.

Using Monte Carlo techniques and some reasonable assumption, it will be demonstrated that the IMS complies fully with the dose limits set by 10CFR32.27.

2.0 Parts of the IMS' life cycle covered by CFR-30.27

The activity in the IMS consists of 3.3 mCi source of Ni^{63} electroplated on a Ni disk, 50 μm in thickness and 0.95 cm in diameter. The disk is mounted inside a cylindrical aluminum housing which consists of two parts. The outside diameter is about 6 cm and the total length is 4 cm. The aluminum thickness is near 1 cm for the side and one end wall. It is thinner (.25 cm) at the end nearest to the source location. In this way, the Ni^{63} source is essentially enclosed in a tamper proof shielding enclosure.

Special assembly components are used during production at the manufacturing location in Canada which prevent opening the cylinder in the field. For servicing and disposal, the unit must be returned to the manufacturer outside the US. Hence, this report is an analysis of the potential radiological risk of the device while in normal use and in accident situations while the instrument is located in the US . It does not cover the radiological risk posed by the manufacture of the IMS.

2.1 The IMS from a radiological protection point of view

It is safe to assume that the current IMS design will be used in the medium term for all systems produced. It is then worth doing a detailed analysis of the ionizing radiation which "leaks" from the aluminum enclosure either in the form of energetic electrons and photons.

The model assumed for the analysis is shown on Figure 1. It shows the relative location of the various components but it is not to scale. In particular, the Nickel disk and the steel screen would be vanishingly small in a realistic schematic.

Ni^{63} is a β emitter with endpoint and average energies of 67 keV and 17 keV respectively. The spectral shape used in this work is from [1]. Potential radiation risk is due to the source β particles and x-ray photons. These photons result from the interaction of the β particles with the surrounding materials, especially the higher Z elements such as the Ni plate and those contained in the steel mesh and they are in the form of bremstrahlung or line radiation. From the geometry shown on Figure 1, it is anticipated that the hottest location will be "A" where the Nickel plate acts as a β to X-ray converter and is located near the thinnest wall of the enclosure.

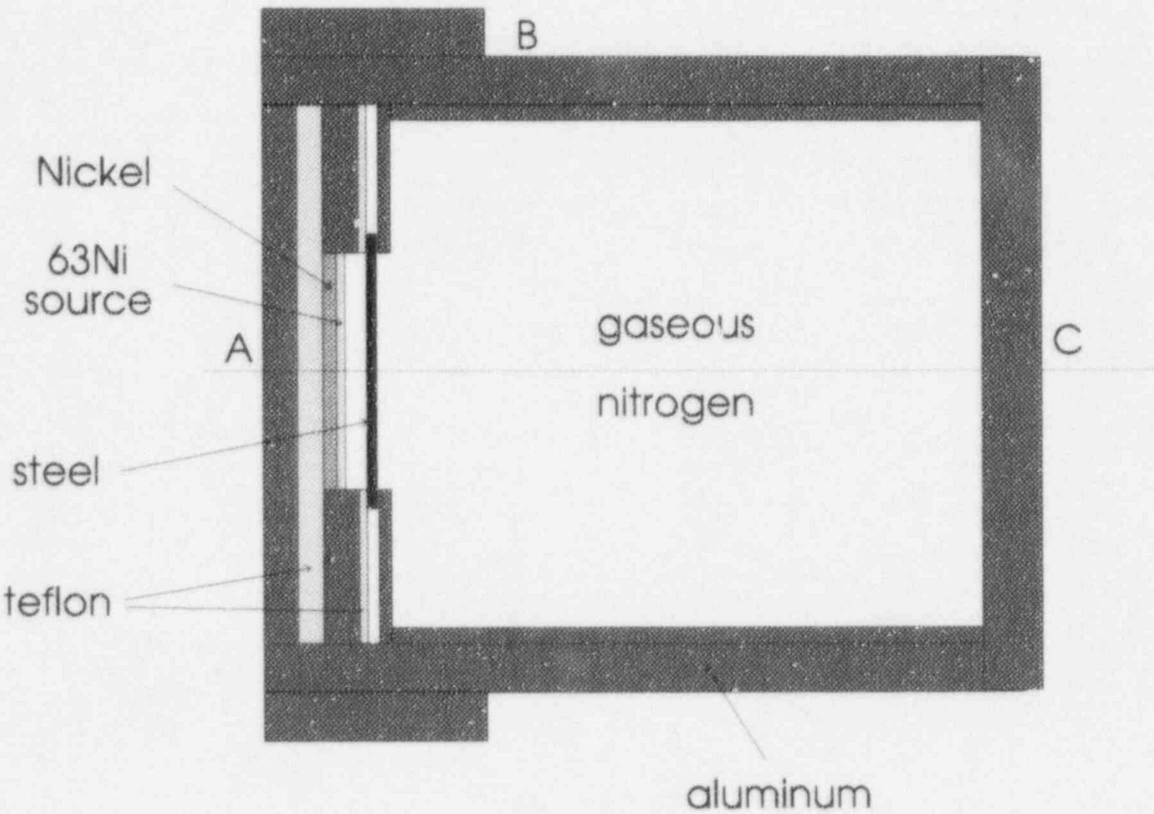

Figure 1: Schematic of the geometry of the IMS used for the purpose of external radiation calculations. Its shows the relative placement of the components but is not to scale. In particular, the thickness' of the nickel plate and the steel mesh are exaggerated.

3.0 Dose rate estimation

3.1 Beta particles

The ranges of β particles in aluminum for energies E from 0.010 MeV to 3 MeV are given by the following empirical equation [2].

$$R = 0.412E^{n} \text{ gm/cm2} \qquad (1)$$
$$n = 1.265 - 0.0954 \ln E$$

The maximum energy electron from Ni^{63} (0.067 MeV) has a range of 25 μm in aluminum. The thinnest wall of the IMS is 100 times thicker than the electron range. We conclude that β particles will not contribute to the external dose during routine use and handling of the IMS.

3.2 X-Ray Photons

In assessing the external dose during routine operation and handling of the IMS, we must keep in mind the categories put forward by the US Nuclear Regulatory Commission in its Rules and Regulations [3], from now on referred to as 10CFR32.27. Specifically, the IMS must comply with the annual extremity dose limit of 7.5 rem and whole body limit of 0.5 rem.

We have opted to assess the external dose rates by the Monte Carlo method. The code used was CYLTRANP of the ITS family of codes [4] developed at the Sandia National Laboratories. These well established coupled electron-photon transport codes are descendants of ETRAN [5], developed at the US National Bureau of Standards. In particular, the CYLTRANP code is well suited for 3-dimensional transport simulation in geometries which have cylindrical geometries. The cut-off energies for both the electron and photons are 1 keV which allows the inclusion of nearly the full β spectrum from Ni^{63}.

Dose rates may be obtained using two methods. The calculations supply the energy spectra of the x-rays which escape from the aluminum cylinder. These may be combined with suitable fluence to dose conversion coefficients [6,7] to yield the dose at any depth in tissue and for any distance away from the IMS. For contact doses, a piece of "standard" human tissue (ICRU tissue: 10.1% {weight fract.} H, 11.1% C, 2.6% N, 76.2% O) is put in contact with the aluminum enclosure and the dose is calculated directly from the energy deposition of photoelectrons in the tissue.

3.3 Potential for Skin (Extremity) Dose

3.3.1 Normal use

In general, particularly for the x-ray energies of interest here, the point of maximum dose is on the surface, as shown by the exposure to dose equivalent conversion factors [7]. The most radiosensitive cells of the skin, if not the whole body, are the germinal or basal layer [8] cells which are located at a mean depth of 70 μm according to ICRP 26 [9]. It also corresponds approximately to the depth of the peak dose for low energy x-ray photons.

At location A, B and C on the IMS (Figure 1), we apply a 1 cm layer of "skin-equivalent" ICRU tissue [10] divided in 3 layers. The first layer, in contact with the IMS, is 70 μm thick and corresponds to the insensitive layer of the skin. The second layer is 20 μm thick and corresponds to the radio-sensitive layer of interest. The rest of the ICRU tissue layer may be thought as a backscattering phantom, roughly the thickness of a finger.

At location "A", the energy deposited below 70 μm in a 6.28 mg mass of ICRU tissue is 1.49×10^{-11} MeV (13% 1 σ) per source β particle. Assuming a quality factor of 1, this is equivalent to 3.80×10^{-17} rem/β. The source has a strength of 3.3 mCi. It emits 4.4×10^{11} β/hour. Hence the skin equivalent dose rate on contact at point "A" is 1.67×10^{-5} rem/hour (13% error).

At location B, the tissue mass in the sensitive layer is put as 36 mg. A 1 cm wide strip of ICRU is applied all around the aluminum cylinder at B. This "simulates" a hand or finger wrapped around the IMS. The deposited energy is 3.6×10^{-13} MeV/β (31%). Repeating the analysis above, this corresponds to 7×10^{-8} rem/hour.

At location C, the tissue mass in the sensitive layer is 6.28 mg. The deposited energy is 1.6×10^{-13} MeV/β (66%). Clearly, in this case the calculation has insufficient statistics to supply a small error. However, it is clear that the highest dose rate is found at "A" and further calculations at C are unnecessary. Nevertheless, this result gives a dose rate of 3×10^{-8} rem/hour.

As expected, the skin dose rate is highest at "A" where the source is closest and the aluminum shielding is the thinnest. At a dose rate of 1.6×10^{-5} rem/hour, a worker cannot exceed the annual extremity dose limit of 7.5 rem even if he is in contact with the source 24 hours a day. In such a case, his total accumulated equivalent dose would be 0.14 rem. This fulfills the requirement for extremity dose of column II, Table 32.28, 10 CFR 32.27.

These low dose rates reemphasize the fact that very few X-rays emerge from inside the shield. In practice, the IMS is a subsystem inside a 1/16" thick steel cabinet. This arrangement ensures that a worker will never be closer than 20 cm from the IMS. The exposure to radiation will become essentially nil.

3.3.2 Accident Situation

The construction of the IMS enclosure is rugged and tamperproof. Moreover, the manufacture of the IMS is performed in Canada. The probability is low that a member of the public in the US will come in contact with the bare Ni^{63} source. If this were to happen and the source was in contact with the skin the following equivalent dose rates would occur:

- if the source is held with the active face towards the skin, a local (extremity) dose rate of 0.84 rem/hour (5%) will result. This was obtained again through Monte Carlo calculations of the dose deposited in ICRU tissue at a depth of 70 μm;
- if the source is held with the inactive side towards the skin, a dose rate of 0.0074 rem/hour (26%) will result.

An unsuspecting individual might carry the source active face towards or away from the skin with equal probability. In this case the useful dose rate is about 0.4 rem/hour. The individual would have to carry the source, against his skin for 18.75 hours in order to exceed the dose limit of 7.5 rem. The probability of this event is **low**. The extremity dose limit of column II, table 32.28 of 10CFR32.27 is fulfilled now for this unusual accident situation. The individual would also require to have the source against his skin for 500 hours of the year (62 working days) in order to exceed the extremity dose limit of column III of table 32.28 of 10CFR32.27. Such accidental exposure requires a string of events: opening of the IMS shield, removal of the source disk and pressing of the source against the skin for an extended length of time. The probability of all these events occurring is **negligible**.

3.4 Dose to the Whole Body and other Organs

3.4.1 Normal use of IMS

The resulting dose equivalent to the skin during normal use of the IMS (subsection 3.3.1) is of less than 0.14 rem/year (constant contact with the source enclosure). This guarantees that the whole body limit of 0.5 rem/year (column II, Table 32.28, 10CFR 32.27) cannot be exceeded, and this for two reasons. First, most regions of the whole body will be distant from the source, thus decreasing further the x-ray flux and the dose. Second, whole body dose is defined at 1 cm depth. The low energy x-rays of concern here yields lower equivalent doses at a 1 cm depth compared to 70 μm (Table C1, ref. [7]). We conclude that, in normal use, the IMS subsystem complies with columns II and III of table 32.28 of 10CFR32.27 for both the *whole body* and other *organs categories*.

3.4.2 Accident Situation

As in section 3.3.2, the highest dose rates may result in the unlikely event that a member of the public in the US comes in proximity to the active side of the Ni^{63} source disk. In

such a circumstance, CYLTRANP simulations provide us with the photon spectrum emitted in a 2π solid angle away from the active side of the source. It is assumed that the contribution of β particles to the whole body dose is negligible since 1 meter of air provides an absorbing layer 50 times thicker than the range of the most energetic 67 keV electrons. The photon spectrum on the active side of the source is given in the next table:

Energy interval (keV)	#photons/(keV*steradian)/β	1 σ (%)
1 - 6.7	8.24x10-6	0
6.7 - 13.5	4.1x10-6	1
13.5 - 20.2	1.49x10-6	1
20.2 - 27.0	6.18x10-7	1
27.0 - 33.8	2.47x10-7	1
33.8 - 40.5	9.15x10-8	1
40.5 - 47.3	3.02x10-8	4
47.3 - 54.0	8.39x10-9	6
54.0 - 60.8	1.88x10-9	8
60.8 - 67.5	1.1x10-10	35

This spectrum is folded with flux to dose equivalent conversion coefficients [6] and a dose rate of $9x10^{-5}$ rem/hour at 1 meter is obtained at a depth of 1 cm in ICRU tissue. A person would have to stay at 1 meter from the source for over 5000 hours in order to exceed the most stringent limit of column II, table 32.28 of 10CFR32.27. The risk of this happening is negligible. A person would have to be located at 1 meter from the source for more than a year in order to exceed the most stringent **annual** limit of column III, table 32.28, 10CFR32.27. This is simply not possible.

Hence, in case of external exposure in an accident situation, none of the limits imposed by 10CFR32.27 will be exceeded.

3.4 Dose Following Ingestion (uptake)

The activity consists of 3.3 mCi of Ni^{63} electroplated on a Nickel substrate. High temperature (1200°C) stress tests and wipe testing of Ni^{63} based smoke detectors reveal that only 0.01%, or .33 μCi of activity would be released in the event of a fire [11]. Such a release in the US would be due to an accidental fire or disposal of the instrument at an incinerator. However, the units are expected to be shipped back to the manufacturer for disposal.

The organ dose due to the uptake by a single individual of 10% of the total activity released by the source in the event of a fire is given in the next table (based on organ dose commitments to exposed persons, table 4.1 of ref. [11]):

Organ	Dose (rem)	10CFR 32.27 limits (column I, table 32.38)
Total body	$1.3x10^{-4}$	$5x10^{-3}$
Liver	$2.8x10^{-4}$	$1.5x10^{-2}$
Bone	$4x10^{-3}$	$1.5x10^{-2}$
Lungs	$3.9x10^{-4}$	$1.5x10^{-2}$

The events which may lead an individual to absorb 10% of the released activity are unlikely. The resulting organ doses following the uptake would still be within the limits of column I, table 32.28 of 10CFR32.27.

4. Storage and Disposal

The IMS is not targeting a wide consumer market. Expected sales are of 50 units a year, with 3.3 mCi of Ni^{63}/unit. Such an activity is more often found in undergraduate teaching laboratory. Full instruments containing the IMS will not be stockpiled in storage. The total activity in any place at one time might be a few times the unit activity of 3.3 mCi.

Disposal will take place in Canada. In the event of the accidental incineration of a unit in the US, it has been shown that organ doses resulting from the uptake will not exceed the limits set by the US regulations.

5.0 Conclusion

Using simple analysis it has been demonstrated that the presence of a Ni^{63} source in the IMS complies with all aspects of 10CFR32.27. In fact, in all cases, the predicted annual doses are orders of magnitude inferior to the annual limits.

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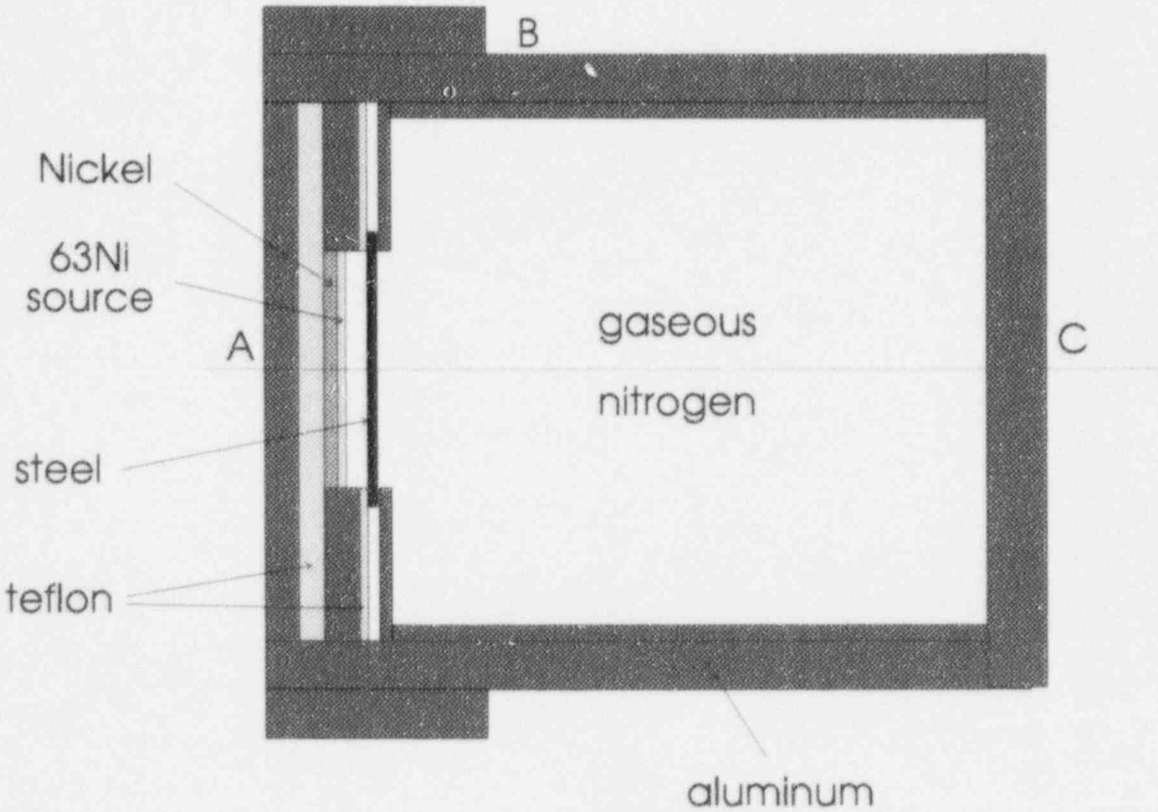

Figure 1: Schematic of the geometry of the IMS used for the purpose of external radiation calculations. Its shows the relative placement of the components but is not to scale. In particular, the thickness' of the nickel plate and the steel mesh are exaggerated.

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The ranges of β particles in aluminum for energies E from 0.010 MeV to 3 MeV are given by the following empirical equation [2].

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An unsuspecting individual might carry the source active face towards or away from the skin with equal probability. In this case the useful dose rate is about 0.4 rem/hour. The individual would have to carry the source, against his skin for 18.75 hours in order to exceed the dose limit of 7.5 rem. The probability of this event is **low**. The extremity dose limit of column II, table 32.28 of 10CFR32.27 is fulfilled now for this unusual accident situation. The individual would also require to have the source against his skin for 500 hours of the year (62 working days) in order to exceed the extremity dose limit of column III of table 32.28 of 10CFR32.27. Such accidental exposure requires a string of events: opening of the IMS shield, removal of the source disk and pressing of the source against the skin for an extended length of time. The probability of all these events occurring is **negligible**.

3.4 Dose to the Whole Body and other Organs

3.4.1 Normal use of IMS

The resulting dose equivalent to the skin during normal use of the IMS (subsection 3.3.1) is of less than 0.14 rem/year (constant contact with the source enclosure). This guarantees that the whole body limit of 0.5 rem/year (column II, Table 32.28, 10CFR 32.27) cannot be exceeded, and this for two reasons. First, most regions of the whole body will be distant from the source, thus decreasing further the x-ray flux and the dose. Second, whole body dose is defined at 1 cm depth. The low energy x-rays of concern here yields lower equivalent doses at a 1 cm depth compared to 70 μm (Table C1, ref. [7]). We conclude that, in normal use, the IMS subsystem complies with columns II and III of table 32.28 of 10CFR32.27 for both the *whole body* and other *organs categories*.

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As in section 3.3.2, the highest dose rates may result in the unlikely event that a member of the public in the US comes in proximity to the active side of the Ni^{63} source disk. In

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54.0 - 60.8	1.88x10-9	8
60.8 - 67.5	1.1x10-10	35

This spectrum is folded with flux to dose equivalent conversion coefficients [6] and a dose rate of 9×10^{-5} rem/hour at 1 meter is obtained at a depth of 1 cm in ICRU tissue. A person would have to stay at 1 meter from the source for over 5000 hours in order to exceed the most stringent limit of column II, table 32.28 of 10CFR32.27. The risk of this happening is negligible. A person would have to be located at 1 meter from the source for more than a year in order to exceed the most stringent **annual** limit of column III, table 32.28, 10CFR32.27. This is simply not possible.

Hence, in case of external exposure in an accident situation, none of the limits imposed by 10CFR32.27 will be exceeded.

3.4 Dose Following Ingestion (uptake)

The activity consists of 3.3 mCi of Ni^{63} electroplated on a Nickel substrate. High temperature (1200°C) stress tests and wipe testing of Ni^{63} based smoke detectors reveal that only 0.01%, or .33 μCi of activity would be released in the event of a fire [11]. Such a release in the US would be due to an accidental fire or disposal of the instrument at an incinerator. However, the units are expected to be shipped back to the manufacturer for disposal.

The organ dose due to the uptake by a single individual of 10% of the total activity released by the source in the event of a fire is given in the next table (based on organ dose commitments to exposed persons, table 4.1 of ref. [11]):

Organ	Dose (rem)	10CFR 32.27 limits (column I, table 32.38)
Total body	1.3×10^{-4}	5×10^{-3}
Liver	2.8×10^{-4}	1.5×10^{-2}
Bone	4×10^{-3}	1.5×10^{-2}
Lungs	3.9×10^{-4}	1.5×10^{-2}

The events which may lead an individual to absorb 10% of the released activity are unlikely. The resulting organ doses following the uptake would still be within the limits of column I, table 32.28 of 10CFR32.27.

4. Storage and Disposal

The IMS is not targeting a wide consumer market. Expected sales are of 50 units a year, with 3.3 mCi of Ni^{63}/unit. Such an activity is more often found in undergraduate teaching laboratory. Full instruments containing the IMS will not be stockpiled in storage. The total activity in any place at one time might be a few times the unit activity of 3.3 mCi.

Disposal will take place in Canada. In the event of the accidental incineration of a unit in the US, it has been shown that organ doses resulting from the uptake will not exceed the limits set by the US regulations.

5.0 Conclusion

Using simple analysis it has been demonstrated that the presence of a Ni^{63} source in the IMS complies with all aspects of 10CFR32.27. In fact, in all cases, the predicted annual doses are orders of magnitude inferior to the annual limits.

References

[1] W.G. Cross, H. Ing, N. Freedman, *A Short Atlas of Beta-Ray Spectra*, Phys. Med. Biol. **28**, p. 1251-1260 (1983).

[2] R.B. Evans, *The Atomic Nucleus*, McGraw-Hill, 1955.

[3] United States Nuclear Regulatory Commission, Rules and Regulations-Title 10, Chapter 1, Code of Federal Regulations- Energy, Part 32.

[4] J.A. Halbleib, R.P. Kensek, T.A. Melhorn, G.D. Valdez, *ITS Version 3.0: The Integrated Tiger Series of Coupled Electron/Photon Monte Carlo Transport Codes*, SAND91-1634, 1992.

[5] M.J. Berger, Chapter 7 of *Monte Carlo Transport of Electrons and Photons*, Eds. T.M. Jenkins, W.R. Nelson and A. Rindi, Plenum Press, 1987.

[6] D.W.O Rogers, Fluence to Dose Equivalent Conversion Factors Calculated with EGS3 for Electrons of 100 keV to 20 GeV and Photons from 11 keV to 20 GeV, Health Physics **46**, p. 891-914 (1984).

[7] American National Standards Institute Inc., *American National Standard for dosimetry-personnel dosimetry performance-criteria testing*, ANSI N13.11-1983.

[8] W.D. Reece, R. Harty, L.W. Brakenbush, P.L. Roberson, *Extremity Monitoring: Considerations for Use, Dosimeter Placement, and Evaluation*, NUREG/CR-4297, PNL-5509, (1985).

[9] International Commission on Radiological Protection, *Recommendations of the International Commission on Radiological Protection*, ICRP Publication 26, Pergamon Press, New-York, 1977.

[10] International Comission on Radiation Units and Measurements, *Radiation Quantities and Units*, ICRU Report 19, Washington, 1971.

[11] R. Belanger, D.W. Buckley, J.B. Swensen, *Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am241*, NUREG/CR11-1156

Brian Smith

CPAB Notes

$R = 412 E^{1.265 - 0.0954 \ln E}$ $E = 0.067$ MeV

$R = 6.71$ mg/cm^2

$\rho_{Al} = 2.7$ g/cm^3

$t_d = \frac{R}{\rho_{Al}} = \frac{0.00671 \text{ g/cm}^2}{2.7 \text{ g/cm}^3} = 2.5 \times 10^{-3}$ cm $= 25\ \mu m$

source surrounded by 2 cm Al → no β's escape

$\rho_{Air} = 1.293$ mg/cm^3

$t_d = \frac{R}{\rho_{Air}} = \frac{6.71 \text{ mg/cm}^2}{1.293 \text{ mg/cm}^3} =$ ~~5.72~~ 5.2 cm

$ALI = 2 \times 10^3\ \mu Ci$ contains 3.3 mCi $ALI = 5$ Rem

$= 2$ mCi

% released = 0.33 μC

$\frac{0.33\ \mu Ci}{2 \times 10^3\ \mu Ci} = 1.65 \times 10^{-4}$

$1.65 \times 10^{-4} \times 5$ rem $= 0.825 \times 10^{-3}$ rem $= 0.825$ mrem

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE FACSIMILE

Date & Time: Friday, November 15, 1996 2:11 PM **Pages To Follow:** 14

Send To

Name: Brian Smith **FAX:** 301-415-5369
Company: NRC Headquarters **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: NRC DEVICE REVIEW (DOSE ASSESSMENT)

Notes: I am sending you the letter that is copied in this fax and the report on the "Dose Assessment" I will be out of the office for a few days starting 18 Nov, so if you have any questions related to the "Dose Assessment", Please feel free to contact Dr. Unny Thekkadath at (613) 228-1145. If there are other questions related to our application please contact Debra Harley at (613) 230-0609 and she can get in touch with me.

As you see we just received a fax telling us that our "Possession License" has been approved.

Thanks for your support.

Sincerely,

A.L. McEachern
Director, Business Development

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

November 15, 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:

Further to my letter dated November 5, 1996 in which I advised you that the answer to the "Dose Assessment" question would follow, I am pleased to send you a report that was completed for us by a reputable consultant. The report speaks for itself, however if you have any questions, please feel free to contact either Al McEachern or myself.

I have been advised that, based on the calculations, if a person held the IMS for 24 hours a day for one year, the radiation received would still be below limits. This is a very comforting fact and further supports our claim that the total system is safe to use. One of our systems was recently dropped when it was being unloaded from a truck - the metal container was damaged and there was no apparent damage to the system itself, however Al McEachern performed a wipe test anyway so an independent laboratory could analyze the wipe sample. The result came back as negative.

I hope the information that we have provided meets your requirement. Thank you for your support.

Yours very truly,

Scott Feagan
President
CPAD Technologies Inc.

CPAD Technologies Inc. 9702260004 1P
56 Slater Street, 8th Floor, Ottawa, Ontario, Canada K1P 5H1
Tel.: 613.230.0609 Fax: 613.230.3605
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DETEC

Dose Assessment of the Ion Mobility Spectrometer Containing Ni^{63}

prepared by: J. Dubeau
November 1996

9702260007 1/pp

182, rue Madaire, Aylmer, Québec, Canada, J9H 1P9, Tél: (819) 685-0500, Fax: (819) 685-9218

Summary

The IMS (Ion Mobility Spectrometer) is used in a system to be manufactured in Canada and soid in the US at a predicted rate of 50 units a year. Each IMS unit will contain 3.3 mCi of Ni^{63}, a β emitter with an endpoint energy of 67 keV. Hence, the instrument must comply with US federal regulations, notably table 32.28 of 10CFR32.27 which provides annual dose equivalent limit for various organs for internal and external exposure to the radioactivity. In this work, established Monte Carlo techniques and published fluence to dose conversion coefficients are used to assess the dose risk in a situation of normal use of the IMS and in an accident situation where the source is outside its shielding enclosure. In all situations, under reasonable assumptions, it is demonstrated that the dose limits set by 10CFR32.27 are not exceeded.

Table of contents

1.0 Introduction

The IMS (Ion Mobility Spectrometer) is used in a system to be manufactured in Canada and sold in the US at a predicted rate of 50 units a year. Each IMS unit will contain Ni^{63}, a β emitter with an endpoint energy of 67 keV. Hence, the instrument must comply with US federal regulations, notably table 32.28 of 10CFR32.27 which provides annual dose equivalent limit for various organs for internal and external exposure to the radioactivity.

The annual equivalent dose limits are listed in table 32.28 of 10CFR32.27. It lists 3 categories of radiation exposure in 3 columns. Column I is concerned by the dose to organs caused by the ingestion or inhalation of radioactive material. Column II give dose limits which are unlikely to be exceeded. We view these as representing dose limits during the normal operation of the IMS. In column III, very high dose limits are given for which there is a negligible risk of exceeding. We view these as dose limits for accident situations. Dose limits in all 3 columns are specified according to exposure to the extremities, the whole body and other organs.

Using Monte Carlo techniques and some reasonable assumption, it will be demonstrated that the IMS complies fully with the dose limits set by 10CFR32.27.

2.0 Parts of the IMS' life cycle covered by CFR-30.27

The activity in the IMS consists of 3.3 mCi source of Ni^{63} electroplated on a Ni disk, 50 um in thickness and 0.95 cm in diameter. The disk is mounted inside a cylindrical aluminum housing which consists of two parts. The outside diameter is about 6 cm and the total length is 4 cm. The aluminum thickness is near 1 cm for the side and one end wall. It is thinner (.25 cm) at the end nearest to the source location. In this way, the Ni^{63} source is essentially enclosed in a tamper proof shielding enclosure.

Special assembly components are used during production at the manufacturing location in Canada which prevent opening the cylinder in the field. For servicing and disposal, the unit must be returned to the manufacturer outside the US. Hence, this report is an analysis of the potential radiological risk of the device while in normal use and in accident situations while the instrument is located in the US. It does not cover the radiological risk posed by the manufacture of the IMS.

2.1 The IMS from a radiological protection point of view

It is safe to assume that the current IMS design will be used in the medium term for all systems produced. It is then worth doing a detailed analysis of the ionizing radiation which "leaks" from the aluminum enclosure either in the form of energetic electrons and photons.

The model assumed for the analysis is shown on Figure 1. It shows the relative location of the various components but it is not to scale. In particular, the Nickel disk and the steel screen would be vanishingly small in a realistic schematic.

Ni^{63} is a β emitter with endpoint and average energies of 67 keV and 17 keV respectively. The spectral shape used in this work is from [1]. Potential radiation risk is due to the source β particles and x-ray photons. These photons result from the interaction of the β particles with the surrounding materials, especially the higher Z elements such as the Ni plate and those contained in the steel mesh and they are in the form of bremstrahlung or line radiation. From the geometry shown on Figure 1, it is anticipated that the hottest location will be "A" where the Nickel plate acts as a β to X-ray converter and is located near the thinnest wall of the enclosure.

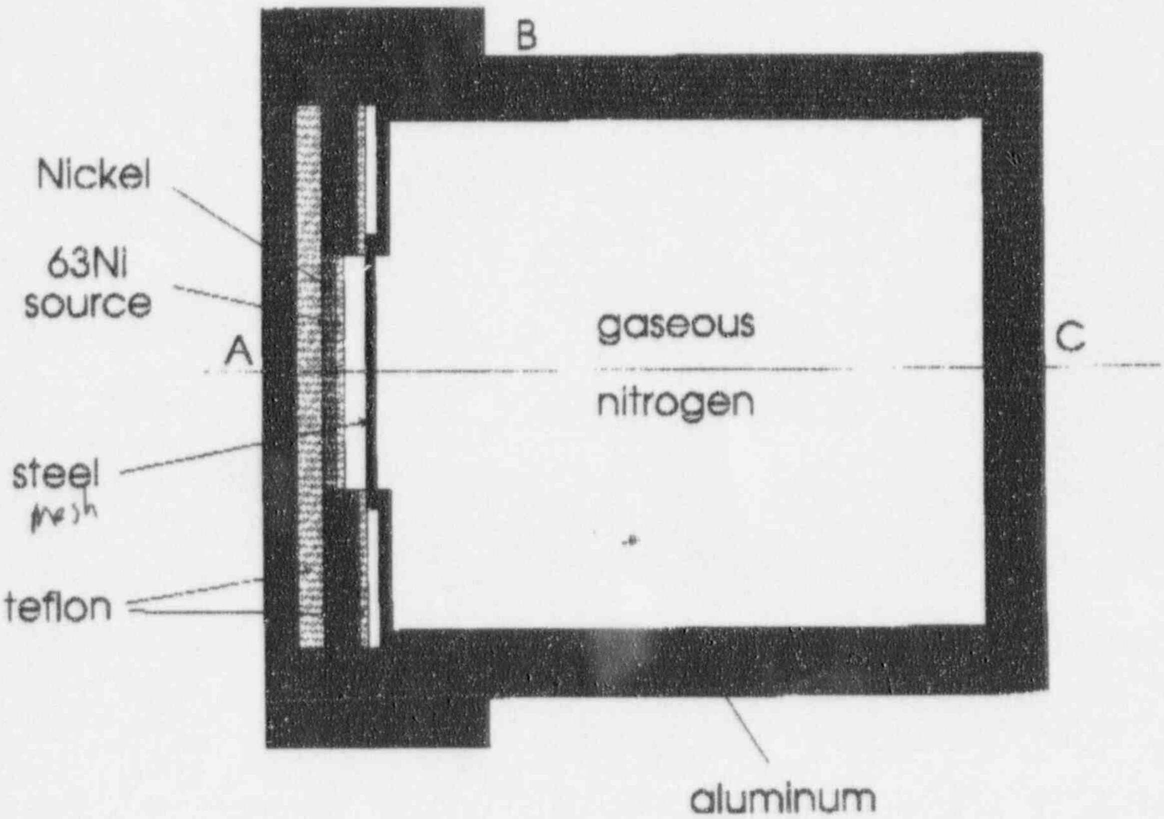

Figure 1: Schematic of the geometry of the IMS used for the purpose of external radiation calculations. Its shows the relative placement of the components but is not to scale. In particular, the thickness' of the nickel plate and the steel mesh are exaggerated.

3.0 Dose rate estimation

3.1 Beta particles

The ranges of β particles in aluminum for energies E from 0.010 MeV to 3 MeV are given by the following empirical equation [2].

$$R = 0.412E^{n} \text{ gm/cm2} \qquad (1)$$
$$n = 1.265 - 0.0954 \ln E$$

Cember
$R = 412\, E^{1.265 - 0.0954 \ln E}$
$= 6.71$ mg/cm²
Al
25 μm

The maximum energy electron from Ni^{63} (0.067 MeV) has a range of 25 μm in aluminum. ✓ The thinnest wall of the IMS is 100 times thicker than the electron range. We conclude that β particles will not contribute to the external dose during routine use and handling of the IMS.

3.2 X-Ray Photons

In assessing the external dose during routine operation and handling of the IMS, we must keep in mind the categories put forward by the US Nuclear Regulatory Commission in its Rules and Regulations [3], from now on referred to as 10CFR32.27. Specifically, the IMS must comply with the annual extremity dose limit of 7.5 rem and whole body limit of 0.5 rem.

Col I → .075 .005

We have opted to assess the external dose rates by the Monte Carlo method. The code used was CYLTRANP of the ITS family of codes [4] developed at the Sandia National Laboratories. These well established coupled electron-photon transport codes are descendants of ETRAN [5], developed at the US National Bureau of Standards. In particular, the CYLTRANP code is well suited for 3-dimensional transport simulation in geometries which have cylindrical geometries. The cut-off energies for both the electron and photons are 1 keV which allows the inclusion of nearly the full β spectrum from Ni^{63}.

Dose rates may be obtained using two methods. The calculations supply the energy spectra of the x-rays which escape from the aluminum cylinder. These may be combined with suitable fluence to dose conversion coefficients [6,7] to yield the dose at any depth in tissue and for any distance away from the IMS. For contact doses, a piece of "standard" human tissue (ICRU tissue: 10.1% {weight fract.} H, 11.1% C, 2.6% N, 76.2% O) is put in contact with the aluminum enclosure and the dose is calculated directly from the energy deposition of photoelectrons in the tissue.

3.3 Potential for Skin (Extremity) Dose

3.3.1 Normal use

In general, particularly for the x-ray energies of interest here, the point of maximum dose is on the surface, as shown by the exposure to dose equivalent conversion factors [7]. The most radiosensitive cells of the skin, if not the whole body, are the germinal or basal layer [8] cells which are located at a mean depth of 70 μm according to ICRP 26 [9] . It also corresponds approximately to the depth of the peak dose for low energy x-ray photons.

At location A, B and C on the IMS (Figure 1), we apply a 1 cm layer of "skin-equivalent" ICRU tissue [10] divided in 3 layers. The first layer, in contact with the IMS, is 70 μm thick and corresponds to the insensitive layer of the skin. The second layer is 20 μm thick and corresponds to the radio-sensitive layer of interest. The rest of the ICRU tissue layer may be thought as a backscattering phantom, roughly the thickness of a finger.

At location "A", the energy deposited below 70 μm in a 6.28 mg mass of ICRU tissue is 1.49×10^{-11} MeV (13% 1 σ) per source β particle. Assuming a quality factor of 1, this is equivalent to 3.80×10^{-17} rem/β. The source has a strength of 3.3 mCi. It emits 4.4×10^{11} β/hour. Hence the skin equivalent dose rate on contact at point "A" is 1.67×10^{-5} rem/hour (13% error).

At location B, the tissue mass in the sensitive layer is put as 36 mg. A 1 cm wide strip of ICRU is applied all around the aluminum cylinder at B. This "simulates" a hand or finger wrapped around the IMS. The deposited energy is 3.6×10^{-13} MeV/β (31%). Repeating the analysis above, this corresponds to 7×10^{-8} rem/hour.

At location C, the tissue mass in the sensitive layer is 6.28 mg. The deposited energy is 1.6×10^{-13} MeV/β (66%). Clearly, in this case the calculation has insufficient statistics to supply a small error. However, it is clear that the highest dose rate is found at "A" and further calculations at C are unnecessary. Nevertheless, this result gives a dose rate of 3×10^{-8} rem/hour.

As expected, the skin dose rate is highest at "A" where the source is closest and the aluminum shielding is the thinnest. At a dose rate of 1.6×10^{-5} rem/hour, a worker cannot exceed the annual extremity dose limit of 7.5 rem even if he is in contact with the source 24 hours a day. In such a case, his total accumulated equivalent dose would be 0.14 rem. This fulfills the requirement for extremity dose of column II, Table 32.28, 10 CFR 32.27.

These low dose rates reemphasize the fact that very few X-rays emerge from inside the shield. In practice, the IMS is a subsystem inside a 1/16" thick steel cabinet. This arrangement ensures that a worker will never be closer than 20 cm from the IMS. The exposure to radiation will become essentially nil.

3.3.2 Accident Situation

The construction of the IMS enclosure is rugged and tamperproof. Moreover, the manufacture of the IMS is performed in Canada. The probability is low that a member of the public in the US will come in contact with the bare Ni^{63} source. If this were to happen and the source was in contact with the skin the following equivalent dose rates would occur:

- if the source is held with the active face towards the skin, a local (extremity) dose rate of 0.84 rem/hour (5%) will result. This was obtained again through Monte Carlo calculations of the dose deposited in ICRU tissue at a depth of 70 μm; SDE
- if the source is held with the inactive side towards the skin, a dose rate of 0.0074 rem/hour (26%) will result.

An unsuspecting individual might carry the source active face towards or away from the skin with equal probability. In this case the useful dose rate is about 0.4 rem/hour. The individual would have to carry the source, against his skin for 18.75 hours in order to exceed the dose limit of 7.5 rem. The probability of this event is **low**. The extremity dose limit of column II, table 32.28 of 10CFR32.27 is fulfilled now for this unusual accident situation. The individual would also require to have the source against his skin for 500 hours of the year (62 working days) in order to exceed the extremity dose limit of column III of table 32.28 of 10CFR32.27. Such accidental exposure requires a string of events: opening of the IMS shield, removal of the source disk and pressing of the source against the skin for an extended length of time. The probability of all these events occurring is **negligible**.

3.4 Dose to the Whole Body and other Organs

3.4.1 Normal use of IMS

The resulting dose equivalent to the skin during normal use of the IMS (subsection 3.3.1) is of less than 0.14 rem/year (constant contact with the source enclosure). This guarantees that the whole body limit of 0.5 rem/year (column II, Table 32.28, 10CFR 32.27) cannot be exceeded, and this for two reasons. First, most regions of the whole body will be distant from the source, thus decreasing further the x-ray flux and the dose. Second, whole body dose is defined at 1 cm depth. The low energy x-rays of concern here yields lower equivalent doses at a 1 cm depth compared to 70 μm (Table C1, ref. [7]). We conclude that, in normal use, the IMS subsystem complies with columns II and III of table 32.28 of 10CFR32.27 for both the *whole body* and other *organs categories*.

Normal is Col. I

3.4.2 Accident Situation

As in section 3.3.2, the highest dose rates may result in the unlikely event that a member of the public in the US comes in proximity to the active side of the Ni^{63} source disk. In

such a circumstance, CYLTRANP simulations provide us with the photon spectrum emitted in a 2π solid angle away from the active side of the source. It is assumed that the contribution of β particles to the whole body dose is negligible since 1 meter of air provides an absorbing layer 50 times thicker than the range of the most energetic 67 keV electrons. The photon spectrum on the active side of the source is given in the next table:
20

Energy interval (keV)	#photons/(keV*steradian)/β	1 σ (%)
1 - 6.7	8.24x10-6	0
6.7 - 13.5	4.1x10-6	1
13.5 - 20.2	1.49x10-6	1
20.2 - 27.0	6.18x10-7	1
27.0 - 33.8	2.47x10-7	1
33.8 - 40.5	9.15x10-8	1
40.5 - 47.3	3.02x10-8	4
47.3 - 54.0	8.39x10-9	6
54.0 - 60.8	1.88x10-9	8
60.8 - 67.5	1.1x10-10	35

This spectrum is folded with flux to dose equivalent conversion coefficients [6] and a dose rate of $9x10^{-5}$ rem/hour at 1 meter is obtained at a depth of 1 cm in ICRU tissue. A person would have to stay at 1 meter from the source for over 5000 hours in order to exceed the most stringent limit of column II, table 32.28 of 10CFR32.27. The risk of this happening is negligible. A person would have to be located at 1 meter from the source for more than a year in order to exceed the most stringent **annual** limit of column III, table 32.28, 10CFR32.27. This is simply not possible.

Hence, in case of external exposure in an accident situation, none of the limits imposed by 10CFR32.27 will be exceeded.

3.4 Dose Following Ingestion (uptake)

The activity consists of 3.3 mCi of Ni^{63} electroplated on a Nickel substrate. High temperature (1200°C) stress tests and wipe testing of Ni^{63} based smoke detectors reveal that only 0.01%, or .33 μCi of activity would be released in the event of a fire [11]. Such a release in the US would be due to an accidental fire or disposal of the instrument at an incinerator. However, the units are expected to be shipped back to the manufacturer for disposal.

The organ dose due to the uptake by a single individual of 10% of the total activity released by the source in the event of a fire is given in the next table (based on organ dose commitments to exposed persons, table 4.1 of ref. [11]):

Organ	Dose (rem)	10CFR 32.27 limits (column I, table 32.38)
Total body	$1.3x10^{-4}$	$5x10^{-3}$
Liver	$2.8x10^{-4}$	$1.5x10^{-2}$
Bone	$4x10^{-3}$	$1.5x10^{-2}$
Lungs	$3.9x10^{-4}$	$1.5x10^{-2}$

The events which may lead an individual to absorb 10% of the released activity are unlikely. The resulting organ doses following the uptake would still be within the limits of column I, table 32.28 of 10CFR32.27.

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The IMS is not targeting a wide consumer market. Expected sales are of 50 units a year, with 3.3 mCi of Ni^{63}/unit. Such an activity is more often found in undergraduate teaching laboratory. Full instruments containing the IMS will not be stockpiled in storage. The total activity in any place at one time might be a few times the unit activity of 3.3 mCi.

Disposal will take place in Canada. In the event of the accidental incineration of a unit in the US, it has been shown that organ doses resulting from the uptake will not exceed the limits set by the US regulations.

5.0 Conclusion

Using simple analysis it has been demonstrated that the presence of a Ni^{63} source in the IMS complies with all aspects of 10CFR32.27. In fact, in all cases, the predicted annual doses are orders of magnitude inferior to the annual limits.

References

[1] W.G. Cross, H. Ing, N. Freedman, *A Short Atlas of Beta-Ray Spectra*, Phys. Med. Biol. **28**, p. 1251-1260 (1983).
[2] R.B. Evans, *The Atomic Nucleus*, McGraw-Hill, 1955.
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[7] American National Standards Institute Inc., *American National Standard for dosimetry-personnel dosimetry performance-criteria testing*, ANSI N13.11-1983.
[8] W.D. Reece, R. Harty, L.W. Brakenbush, P.L. Roberson, *Extremity Monitoring: Considerations for Use, Dosimeter Placement, and Evaluation*, NUREG/CR-4297, PNL-5509, (1985).
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STATE OF NEW YORK - DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH

RADIOACTIVE MATERIALS LICENSE

DL 96-304

PURSUANT TO THE LABOR LAW AND INDUSTRIAL CODE RULE 38, AND IN RELIANCE ON STATEMENTS AND REPRESENTATIONS HERETOFORE MADE BY THE LICENSEE DESIGNATED BELOW. A LICENSE IS HEREBY ISSUED AUTHORIZING SUCH LICENSEE TO RECEIVE, POSSESS, USE AND TRANSFER RADIOACTIVE MATERIAL(S) DESIGNATED BELOW; AND TO USE SUCH RADIOACTIVE MATERIAL(S) FOR THE PURPOSE(S) AND AT THE PLACE(S) DESIGNATED BELOW. THIS LICENSE IS SUBJECT TO ALL APPLICABLE RULES, REGULATIONS, AND ORDERS NOW OR HEREAFTER IN EFFECT OF ALL APPROPRIATE REGULATORY AGENCIES AND TO ANY CONDITIONS SPECIFIED BELOW.

1. NAME OF LICENSEE

CPAD Technologies, Inc.

PHONE:(315)432-0506

3. LICENSE NUMBER

2753-3996

4. EXPIRATION DATE

November 31, 1999

2. ADDRESS OF LICENSEE

The Galson Building
6601 Kirkville Rd.
East Syracuse, New York 13057

5a. REFERENCE No. 1

b. AMENDMENT No. —

6. RADIOACTIVE MATERIALS (element in mass number)	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME
A. Nickel 63	A. Sealed Sources (NRD model N1001)	A. 3.3 millicuries per device.

9. Authorized use:

A. Posession incident to exempt distribution of CPAD Technologies, Inc. Orion Explosives Detection Systems and Sirius Narcotics and Explosives Detection Systems, under licensure of the United States Nuclear Regulatory Commission.

10. Licensed material shall be stored at the installation specified in Condition 2 of this license.

11. A. The Radiation Safety Officer for this license is **A. L. McEachern.**

B. The Radiation Safety Officer for Galson Corporation, license number 2260-3047, shall be the site Radiation Safety Officer for this license.

STATE OF NEW YORK - DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number 2753 3996 5a. Ref. No. 1 b.. Amend. No. —

12. The licensee shall conduct, or have conducted, a periodic inventory of all devices possessed under this license. Such inventory shall be conducted at intervals not to exceed six months and shall be documented in a record containing the identity of each device (make, model and serial number), its location, and the identity of the person who performed the inventory.

13. The licensee shall report immediately by telephone, the loss of control of any radioactive source or device. This includes inability to locate a source or device on your premises, or failure of a source or device to arrive at a destination to which you have shipped it, at the expected time.

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including enclosures, listed below. The Department's Regulations shall govern unless these statements, representations and procedures are more restrictive than the Regulations.

    A. Application dated October 11, 1996, signed by Mariusz Rybak, CEO for CPAD Technologies, and Mike Lorenz, President for Galson Corporation.

John E. Sweeney
COMMISSIONER OF LABOR

DATE: 11/15/96
CJB:wp

by: Clayton J. Bradt
Associate Radiophysicist

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

FACSIMILE FACSIMILE

CPAD TECHNOLOGIES INC.

Date & Time: Friday, November 15, 1996 2:11 PM **Pages To Follow:** 14

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Company: NRC Headquarters **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: NRC DEVICE REVIEW (DOSE ASSESSMENT)

Notes: I am sending you the letter that is copied in this fax and the report on the "Dose Assessment" I will be out of the office for a few days starting 18 Nov, so if you have any questions related to the "Dose Assessment", Please feel free to contact Dr. Unny Thekkadath at (613) 228-1145. If there are other questions related to our application please contact Debra Harley at (613) 230-0609 and she can get in touch with me.

As you see we just received a fax telling us that our "Possession License" has been approved.

Thanks for your support.

Sincerely,

A.L. McEachern
Director, Business Development

WE HAVE MOVED, PLEASE CHECK OUR NEW ADDRESS!

CPAD TECHNOLOGIES INC.

November 15, 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:

Further to my letter dated November 5, 1996 in which I advised you that the answer to the "Dose Assessment" question would follow, I am pleased to send you a report that was completed for us by a reputable consultant. The report speaks for itself, however if you have any questions, please feel free to contact either Al McEachern or myself.

I have been advised that, based on the calculations, if a person held the IMS for 24 hours a day for one year, the radiation received would still be below limits. This is a very comforting fact and further supports our claim that the total system is safe to use. One of our systems was recently dropped when it was being unloaded from a truck - the metal container was damaged and there was no apparent damage to the system itself, however Al McEachern performed a wipe test anyway so an independent laboratory could analyze the wipe sample. The result came back as negative.

I hope the information that we have provided meets your requirement. Thank you for your support.

Yours very truly,

Scott Feagan
President
CPAD Technologies Inc.

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CPAD Technologies Inc.
66 Slater Street, 8th Floor, Ottawa, Ontario, Canada K1P 5H1
Tel.: 613.230.0609 Fax: 613.230.3605
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DETEC

Dose Assessment of the Ion Mobility Spectrometer Containing Ni^{63}

prepared by: J. Dubeau
November 1996

9702260007 13pp.

182, rue Madaire, Aylmer, Québec, Canada, J9H 1P9, Tél: (819) 685-0500, Fax: (819) 685-9218

Summary

The IMS (Ion Mobility Spectrometer) is used in a system to be manufactured in Canada and sold in the US at a predicted rate of 50 units a year. Each IMS unit will contain 3.3 mCi of Ni^{63}, a β emitter with an endpoint energy of 67 keV. Hence, the instrument must comply with US federal regulations, notably table 32.28 of 10CFR32.27 which provides annual dose equivalent limit for various organs for internal and external exposure to the radioactivity. In this work, established Monte Carlo techniques and published fluence to dose conversion coefficients are used to assess the dose risk in a situation of normal use of the IMS and in an accident situation where the source is outside its shielding enclosure. In all situations, under reasonable assumptions, it is demonstrated that the dose limits set by 10CFR32.27 are not exceeded.

Table of contents

1.0 Introduction

The IMS (Ion Mobility Spectrometer) is used in a system to be manufactured in Canada and sold in the US at a predicted rate of 50 units a year. Each IMS unit will contain Ni^{63}, a β emitter with an endpoint energy of 67 keV. Hence, the instrument must comply with US federal regulations, notably table 32.28 of 10CFR32.27 which provides annual dose equivalent limit for various organs for internal and external exposure to the radioactivity.

The annual equivalent dose limits are listed in table 32.28 of 10CFR32.27. It lists 3 categories of radiation exposure in 3 columns. Column I is concerned by the dose to organs caused by the ingestion or inhalation of radioactive material. Column II give dose limits which are unlikely to be exceeded. We view these as representing dose limits during the normal operation of the IMS. In column III, very high dose limits are given for which there is a negligible risk of exceeding. We view these as dose limits for accident situations. Dose limits in all 3 columns are specified according to exposure to the extremities, the whole body and other organs.

Using Monte Carlo techniques and some reasonable assumption, it will be demonstrated that the IMS complies fully with the dose limits set by 10CFR32.27.

2.0 Parts of the IMS' life cycle covered by CFR-30.27

The activity in the IMS consists of 3.3 mCi source of Ni^{63} electroplated on a Ni disk, 50 um in thickness and 0.95 cm in diameter. The disk is mounted inside a cylindrical aluminum housing which consists of two parts. The outside diameter is about 6 cm and the total length is 4 cm. The aluminum thickness is near 1 cm for the side and one end wall. It is thinner (.25 cm) at the end nearest to the source location. In this way, the Ni^{63} source is essentially enclosed in a tamper proof shielding enclosure.

Special assembly components are used during production at the manufacturing location in Canada which prevent opening the cylinder in the field. For servicing and disposal, the unit must be returned to the manufacturer outside the US. Hence, this report is an analysis of the potential radiological risk of the device while in normal use and in accident situations while the instrument is located in the US . It does not cover the radiological risk posed by the manufacture of the IMS.

2.1 The IMS from a radiological protection point of view

It is safe to assume that the current IMS design will be used in the medium term for all systems produced. It is then worth doing a detailed analysis of the ionizing radiation which "leaks" from the aluminum enclosure either in the form of energetic electrons and photons.

The model assumed for the analysis is shown on Figure 1. It shows the relative location of the various components but it is not to scale. In particular, the Nickel disk and the steel screen would be vanishingly small in a realistic schematic.

Ni^{63} is a β emitter with endpoint and average energies of 67 keV and 17 keV respectively. The spectral shape used in this work is from [1]. Potential radiation risk is due to the source β particles and x-ray photons. These photons result from the interaction of the β particles with the surrounding materials, especially the higher Z elements such as the Ni plate and those contained in the steel mesh and they are in the form of bremstrahlung or line radiation. From the geometry shown on Figure 1, it is anticipated that the hottest location will be "A" where the Nickel plate acts as a β to X-ray converter and is located near the thinnest wall of the enclosure.

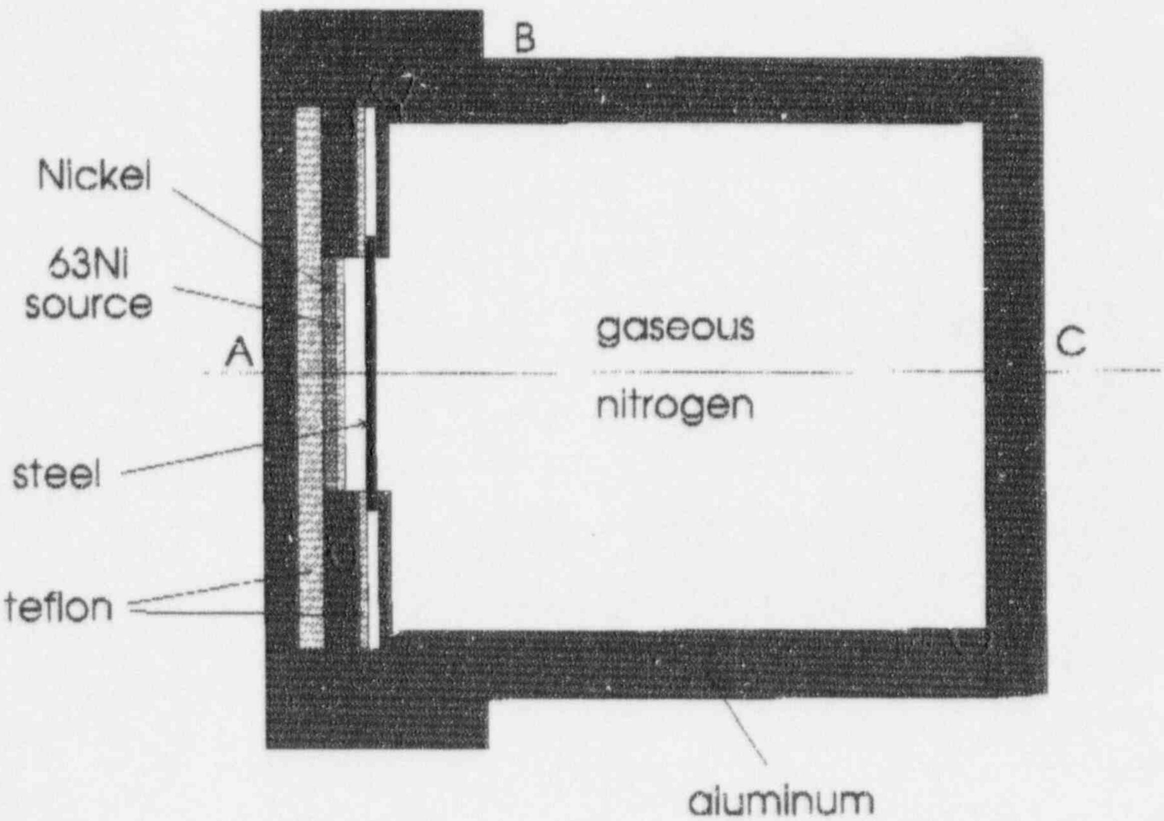

Figure 1: Schematic of the geometry of the IMS used for the purpose of external radiation calculations. Its shows the relative placement of the components but is not to scale. In particular, the thickness' of the nickel plate and the steel mesh are exaggerated.

3.0 Dose rate estimation

3.1 Beta particles

The ranges of β particles in aluminum for energies E from 0.010 MeV to 3 MeV are given by the following empirical equation [2].

$$R = 0.412E^{n} \text{ gm/cm2} \qquad (1)$$
$$n = 1.265 - 0.0954 \ln E$$

The maximum energy electron from Ni^{63} (0.067 MeV) has a range of 25 μm in aluminum. The thinnest wall of the IMS is 100 times thicker than the electron range. We conclude that β particles will not contribute to the external dose during routine use and handling of the IMS.

3.2 X-Ray Photons

In assessing the external dose during routine operation and handling of the IMS, we must keep in mind the categories put forward by the US Nuclear Regulatory Commission in its Rules and Regulations [3], from now on referred to as 10CFR32.27. Specifically, the IMS must comply with the annual extremity dose limit of 7.5 rem and whole body limit of 0.5 rem.

We have opted to assess the external dose rates by the Monte Carlo method. The code used was CYLTRANP of the ITS family of codes [4] developed at the Sandia National Laboratories. These well established coupled electron-photon transport codes are descendants of ETRAN [5], developed at the US National Bureau of Standards. In particular, the CYLTRANP code is well suited for 3-dimensional transport simulation in geometries which have cylindrical geometries. The cut-off energies for both the electron and photons are 1 keV which allows the inclusion of nearly the full β spectrum from Ni^{63}.

Dose rates may be obtained using two methods. The calculations supply the energy spectra of the x-rays which escape from the aluminum cylinder. These may be combined with suitable fluence to dose conversion coefficients [6,7] to yield the dose at any depth in tissue and for any distance away from the IMS. For contact doses, a piece of "standard" human tissue (ICRU tissue: 10.1% {weight fract.} H, 11.1% C, 2.6% N, 76.2% O) is put in contact with the aluminum enclosure and the dose is calculated directly from the energy deposition of photoelectrons in the tissue.

3.3 Potential for Skin (Extremity) Dose

3.3.1 Normal use

In general, particularly for the x-ray energies of interest here, the point of maximum dose is on the surface, as shown by the exposure to dose equivalent conversion factors [7]. The most radiosensitive cells of the skin, if not the whole body, are the germinal or basal layer [8] cells which are located at a mean depth of 70 μm according to ICRP 26 [9] . It also corresponds approximately to the depth of the peak dose for low energy x-ray photons.

At location A, B and C on the IMS (Figure 1), we apply a 1 cm layer of "skin-equivalent" ICRU tissue [10] divided in 3 layers. The first layer, in contact with the IMS, is 70 μm thick and corresponds to the insensitive layer of the skin. The second layer is 20 μm thick and corresponds to the radio-sensitive layer of interest. The rest of the ICRU tissue layer may be thought as a backscattering phantom, roughly the thickness of a finger.

At location "A", the energy deposited below 70 μm in a 6.28 mg mass of ICRU tissue is 1.49×10^{-11} MeV (13% 1 σ) per source β particle. Assuming a quality factor of 1, this is equivalent to 3.80×10^{-17} rem/β. The source has a strength of 3.3 mCi. It emits 4.4×10^{11} β/hour. Hence the skin equivalent dose rate on contact at point "A" is 1.67×10^{-5} rem/hour (13% error).

At location B, the tissue mass in the sensitive layer is put as 36 mg. A 1 cm wide strip of ICRU is applied all around the aluminum cylinder at B. This "simulates" a hand or finger wrapped around the IMS. The deposited energy is 3.6×10^{-13} MeV/β (31%). Repeating the analysis above, this corresponds to 7×10^{-8} rem/hour.

At location C, the tissue mass in the sensitive layer is 6.28 mg. The deposited energy is 1.6×10^{-13} MeV/β (66%). Clearly, in this case the calculation has insufficient statistics to supply a small error. However, it is clear that the highest dose rate is found at "A" and further calculations at C are unnecessary. Nevertheless, this result gives a dose rate of 3×10^{-8} rem/hour.

As expected, the skin dose rate is highest at "A" where the source is closest and the aluminum shielding is the thinnest. At a dose rate of 1.6×10^{-5} rem/hour, a worker cannot exceed the annual extremity dose limit of 7.5 rem even if he is in contact with the source 24 hours a day. In such a case, his total accumulated equivalent dose would be 0.14 rem. This fulfills the requirement for extremity dose of column II, Table 32.28, 10 CFR 32.27.

These low dose rates reemphasize the fact that very few X-rays emerge from inside the shield. In practice, the IMS is a subsystem inside a 1/16" thick steel cabinet. This arrangement ensures that a worker will never be closer than 20 cm from the IMS. The exposure to radiation will become essentially nil.

3.3.2 Accident Situation

The construction of the IMS enclosure is rugged and tamperproof. Moreover, the manufacture of the IMS is performed in Canada. The probability is low that a member of the public in the US will come in contact with the bare Ni^{63} source. If this were to happen and the source was in contact with the skin the following equivalent dose rates would occur:

- if the source is held with the active face towards the skin, a local (extremity) dose rate of 0.84 rem/hour (5%) will result. This was obtained again through Monte Carlo calculations of the dose deposited in ICRU tissue at a depth of 70 μm;
- if the source is held with the inactive side towards the skin, a dose rate of 0.0074 rem/hour (26%) will result.

An unsuspecting individual might carry the source active face towards or away from the skin with equal probability. In this case the useful dose rate is about 0.4 rem/hour. The individual would have to carry the source, against his skin for 18.75 hours in order to exceed the dose limit of 7.5 rem. The probability of this event is **low**. The extremity dose limit of column II, table 32.28 of 10CFR32.27 is fulfilled now for this unusual accident situation. The individual would also require to have the source against his skin for 500 hours of the year (62 working days) in order to exceed the extremity dose limit of column III of table 32.28 of 10CFR32.27. Such accidental exposure requires a string of events: opening of the IMS shield, removal of the source disk and pressing of the source against the skin for an extended length of time. The probability of all these events occurring is **negligible**.

3.4 Dose to the Whole Body and other Organs

3.4.1 Normal use of IMS

The resulting dose equivalent to the skin during normal use of the IMS (subsection 3.3.1) is of less than 0.14 rem/year (constant contact with the source enclosure). This guarantees that the whole body limit of 0.5 rem/year (column II, Table 32.28, 10CFR 32.27) cannot be exceeded, and this for two reasons. First, most regions of the whole body will be distant from the source, thus decreasing further the x-ray flux and the dose. Second, whole body dose is defined at 1 cm depth. The low energy x-rays of concern here yields lower equivalent doses at a 1 cm depth compared to 70 μm (Table C1, ref. [7]). We conclude that, in normal use, the IMS subsystem complies with columns II and III of table 32.28 of 10CFR32.27 for both the *whole body* and other *organs categories*.

3.4.2 Accident Situation

As in section 3.3.2, the highest dose rates may result in the unlikely event that a member of the public in the US comes in proximity to the active side of the Ni^{63} source disk. In

such a circumstance, CYLTRANP simulations provide us with the photon spectrum emitted in a 2π solid angle away from the active side of the source. It is assumed that the contribution of β particles to the whole body dose is negligible since 1 meter of air provides an absorbing layer 50 times thicker than the range of the most energetic 67 keV electrons. The photon spectrum on the active side of the source is given in the next table:

Energy interval (keV)	#photons/(keV*steradian)/β	1 σ (%)
1 - 6.7	8.24x10-6	0
6.7 - 13.5	4.1x10-6	1
13.5 - 20.2	1.49x10-6	1
20.2 - 27.0	6.18x10-7	1
27.0 - 33.8	2.47x10-7	1
33.8 - 40.5	9.15x10-8	1
40.5 - 47.3	3.02x10-8	4
47.3 - 54.0	8.39x10-9	6
54.0 - 60.8	1.88x10-9	8
60.8 - 67.5	1.1x10-10	35

This spectrum is folded with flux to dose equivalent conversion coefficients [6] and a dose rate of 9×10^{-5} rem/hour at 1 meter is obtained at a depth of 1 cm in ICRU tissue. A person would have to stay at 1 meter from the source for over 5000 hours in order to exceed the most stringent limit of column II, table 32.28 of 10CFR32.27. The risk of this happening is negligible. A person would have to be located at 1 meter from the source for more than a year in order to exceed the most stringent annual limit of column III, table 32.28, 10CFR32.27. This is simply not possible.

Hence, in case of external exposure in an accident situation, none of the limits imposed by 10CFR32.27 will be exceeded.

3.4 Dose Following Ingestion (uptake)

The activity consists of 3.3 mCi of Ni^{63} electroplated on a Nickel substrate. High temperature (1200°C) stress tests and wipe testing of Ni^{63} based smoke detectors reveal that only 0.01%, or .33 μCi of activity would be released in the event of a fire [11]. Such a release in the US would be due to an accidental fire or disposal of the instrument at an incinerator. However, the units are expected to be shipped back to the manufacturer for disposal.

The organ dose due to the uptake by a single individual of 10% of the total activity released by the source in the event of a fire is given in the next table (based on organ dose commitments to exposed persons, table 4.1 of ref. [11]):

Organ	Dose (rem)	10CFR 32.27 limits (column I, table 32.38)
Total body	$1.3x10^{-4}$	$5x10^{-3}$
Liver	$2.8x10^{-4}$	$1.5x10^{-2}$
Bone	$4x10^{-3}$	$1.5x10^{-2}$
Lungs	$3.9x10^{-4}$	$1.5x10^{-2}$

The events which may lead an individual to absorb 10% of the released activity are unlikely. The resulting organ doses following the uptake would still be within the limits of column I, table 32.28 of 10CFR32.27.

4. Storage and Disposal

The IMS is not targeting a wide consumer market. Expected sales are of 50 units a year, with 3.3 mCi of Ni^{63}/unit. Such an activity is more often found in undergraduate teaching laboratory. Full instruments containing the IMS will not be stockpiled in storage. The total activity in any place at one time might be a few times the unit activity of 3.3 mCi.

Disposal will take place in Canada. In the event of the accidental incineration of a unit in the US, it has been shown that organ doses resulting from the uptake will not exceed the limits set by the US regulations.

5.0 Conclusion

Using simple analysis it has been demonstrated that the presence of a Ni^{63} source in the IMS complies with all aspects of 10CFR32.27. In fact, in all cases, the predicted annual doses are orders of magnitude inferior to the annual limits.

References

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[10] International Comission on Radiation Units and Measurements, *Radiation Quantities and Units*, ICRU Report 19, Washington, 1971.
[11] R. Belanger, D.W. Buckley, J.B. Swensen, *Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am241*, NUREG/CR11-1156

STATE OF NEW YORK - DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH

RADIOACTIVE MATERIALS LICENSE

DL 96-304

PURSUANT TO THE LABOR LAW AND INDUSTRIAL CODE RULE 38, AND IN RELIANCE ON STATEMENTS AND REPRESENTATIONS HERETOFORE MADE BY THE LICENSEE DESIGNATED BELOW, A LICENSE IS HEREBY ISSUED AUTHORIZING SUCH LICENSEE TO RECEIVE, POSSESS, USE AND TRANSFER RADIOACTIVE MATERIAL(S) DESIGNATED BELOW; AND TO USE SUCH RADIOACTIVE MATERIAL(S) FOR THE PURPOSE(S) AND AT THE PLACE(S) DESIGNATED BELOW. THIS LICENSE IS SUBJECT TO ALL APPLICABLE RULES, REGULATIONS, AND ORDERS NOW OR HEREAFTER IN EFFECT OF ALL APPROPRIATE REGULATORY AGENCIES AND TO ANY CONDITIONS SPECIFIED BELOW.

1. NAME OF LICENSEE CPAD Technologies, Inc. PHONE:(315)432-0506	3. LICENSE NUMBER 2753-3996
	4. EXPIRATION DATE November 31, 1999
2. ADDRESS OF LICENSEE The Galson Building 6601 Kirkville Rd. East Syracuse, New York 13057	5a. REFERENCE No. 1 / b. AMENDMENT No. —

6. RADIOACTIVE MATERIALS (element in mass number)	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME
A. Nickel 63	A. Sealed Sources (NRD model N1001)	A. 3.3 millicuries per device.

9. Authorized use:

A. Posession incident to exempt distribution of CPAD Technologies, Inc. Orion Explosives Detection Systems and Sirius Narcotics and Explosives Detection Systems, under licensure of the United States Nuclear Regulatory Commission.

10. Licensed material shall be stored at the installation specified in Condition 2 of this license.

11. A. The Radiation Safety Officer for this license is **A. L. McEachern.**

B. The Radiation Safety Officer for Galson Corporation, license number 2260-3047, shall be the site Radiation Safety Officer for this license.

STATE OF NEW YORK - DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number 2753 3996 5a. Ref. No. 1 b.. Amend. No. —

12. The licensee shall conduct, or have conducted, a periodic inventory of all devices possessed under this license. Such inventory shall be conducted at intervals not to exceed six months and shall be documented in a record containing the identity of each device (make, model and serial number), its location, and the identity of the person who performed the inventory.

13. The licensee shall report immediately by telephone, the loss of control of any radioactive source or device. This includes inability to locate a source or device on your premises, or failure of a source or device to arrive at a destination to which you have shipped it, at the expected time.

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including enclosures, listed below. The Department's Regulations shall govern unless these statements, representations and procedures are more restrictive than the Regulations.

    A. Application dated October 11, 1996, signed by Mariusz Rybak, CEO for CPAD Technologies, and Mike Lorenz, President for Galson Corporation.

John E. Sweeney
COMMISSIONER OF LABOR

DATE: 11/15/96
CJB:wp

by: Clayton J. Bradt
Associate Radiophysicist

CPAD TECHNOLOGIES INC.

November 5, 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:

Further to the discussions that you have had with members of my staff pertaining to the Quality Assurance Program for the manufacture of our Explosives Detection System and, more specifically, the "device" containing the Ni - 63, let me assure you that we are committed to producing a quality product and will incorporate the unique requirements that will comply with the NRC regulations as specified in the Regulatory Guide 6.9.

Enclosed with this letter is a copy of CPAD's Quality Assurance Manual, which gives an overview of the areas that our Quality Control System will encompass and the designation of responsibility. Our quality control procedures will detail all the specific processes which meet the requirements of the Regulatory Guide 6.9. CPAD Technologies Inc. will also adhere to the requirements outlined in Annex "C" of the afore-mentioned guide. This annex specifies the following statements which CPAD Technologies commits to adhere to:

a) to ensure that CPAD Technologies will follow the specifications identified for detector manufacturers;
b) to perform "Lot Tolerance Percent Defective" (LTPD) 5% inspection sampling for point of sale package labelling conformance; and
c) perform LTPD 5% sampling as per the modified tables for design conformance and removable contamination.

CPAD Technologies will be testing 100% of the detectors that it manufactures for removable contamination prior to shipment to the distributor or customer.

9702250416 2pp

CPAD Technologies Inc.

66 Slater Street, 6th Floor, Ottawa, Ontario, Canada K1P 5H1 Tel.: 613.230.0609 Fax: 613.230.3805
E-mail: cpadtech@cpadtech.com

I realize that we must still answer the "Dose Assessment" question, which will be completed later this week. However, rather than delay our response, I am sending you the enclosed so that you may include it in your review. If you have any questions, please do not hesitate to contact Al McEachern or myself. Thank you for your support.

Yours very truly,

Scott Feagan
President
CPAD Technologies Inc.