



RECEIVED
REGION 1

7/7/04

'04 JUL -9 P1 :42

Q-2

To: Nuclear Regulatory Commission

RE: Notification of Completion of License Termination Survey at Immunicon (Materials License Number 37-20963-01)

Dear NRC,

03022159

Immunicon is has completed a license termination survey on 6/17/04 through Porter consultants, Inc., (Certified Health Physicist, Ph# 610 896-5353). Please find the report there of.

The report concludes: "The only radionuclide in use at the Immunicon Facility is P-32 and it was last received on 1/15/04. Decay calculations show that the inventory on hand has decayed to a quantity well below the exempt quantity for P-32. It has also been shown that the activity remaining in the facility could not cause the guideline level to be exceeded even if it were released in the room rather than being contained in its locked container.

A survey of the "maximum likelihood" locations revealed no measurable radioactivity above instrument background. Porter Consultants therefore concludes that the facility meets the 25 mrem per year decommissioning criteria and can be released for unrestricted use."

Please let us know if there are any further actions we need to take to satisfy this decommission.

Thank you for your attention to this matter.

A handwritten signature in cursive script, appearing to read "S. Mark O'Hara".

S. Mark O'Hara, Ph.D.

Radiation Safety Officer

Immunicon Corp.

3400 Masons Mill Rd.

Huntingdon Valley, PA 190-06

Ph215 830-0777, x-103

135124

NMSS/RONI MATERIALS-002

This is to acknowledge the receipt of your letter/application dated

6/7/04, and to inform you that the initial processing which includes an administrative review has been performed.

TEAM. 37-20963-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

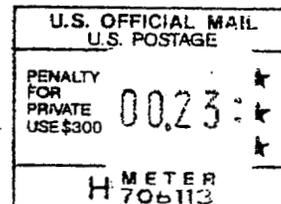
Your action has been assigned Mail Control Number 135124.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA PA 19406-1415

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE \$300



Shawn Mark O'Hara, Ph.D.
Radiation Safety Officer
Immunicon Corporation
3400 Masons Mill Road
Huntingdon Valley, PA 19006





Porter Consultants, Inc.
125 Argyle Road
Ardmore, PA 19003-3201
Phone (610) 896-5353
FAX (610) 642-7804

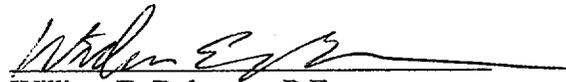
PCI TR-481

LICENSE TERMINATION SURVEY
IMMUNICON FACILITY
BUILDINGS 1 AND 2
MASONS MILL BUSINESS PARK
HUNTINGTON VALLEY, PA

Draft Report Date 6/17/04

Survey Date 6/17/04

PREPARED BY

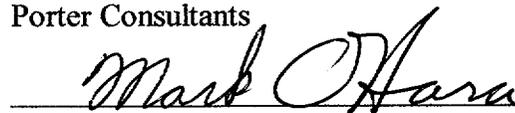

William E. Belanger, P.E.

Health Physicist and Registered Professional Engineer

REVIEWED BY


S. W. Porter, CHP, President
Porter Consultants

APPROVED BY


Mark O'Hara, Radiation Safety Officer
Immunicon

I Site History

This radiation license termination survey was performed on June 17, 2004 at the request of Mark O'Hara, the Radiation Safety Officer at the Immunicon facility in Huntington Valley, PA. Two previous survey were performed by Porter Consultants, one in 1999 and another on December 4, 2003. The 1999 survey included rooms that are no longer used in the handling or storage of radioactive materials. The radioactive material used at the previous location included I-125 with a 60 day half life. Since several years have passed since this location was used for radioactive materials (more than ten half lives,) it can be safely assumed that any residual contamination has decayed away.

Since the 1999 survey, the radioactive materials used at the facility have changed. Most notably, neither Iodine 125 nor any other isotope of iodine is used at the facility, and iodine isotopes have been removed from the NRC materials license. While the license allows Immunicon to use 10 millicuries of Phosphorous 32 (P-32), 10 millicuries of Phosphorous 33 (P-33) and 10 millicuries of Sulfur 35 (S-35), only P-32 is or has been in use at the facility.

All handling of radioactive material occurs in one room, Room 162. The P-32 shipment is received and checked for exterior contamination, and from that point spends its entire life in that room. The material is held there for decay. There is no movement of radioactive material outside the room after it is received, and no shipment of radioactive waste from the facility. The fact that there is only one non-volatile isotope used in one room greatly simplified the survey.

II Inventory of Radioactive Materials

A physical check of the inventory actually on hand corresponded to the receipt records. For each record of material received, there was a properly labeled container in inventory.

The NRC license allows a total of 10 millicuries of P-32. Containers on hand include the following:

Isotope	Rate Received	Quantity received	Activity as of 06/17/04
P-32	1/24/03	0.25 mCi	4.5E-12 mCi
P-32	3/12/03	0.25 mCi	4.4E-11 mCi
P-32	4/4/03	0.25 mCi	1.3E-10 mCi
P-32	5/16/03	0.25 mCi	1.0E-9 mCi
P-32	7/10/03	0.25 mCi	1.5E-8 mCi
P-32	10/3/03	0.25 mCi	9.2E-7 mCi
P-32	1/15/04	0.25 mCi	1.42E-4 mCi

While small quantities of the received P-32 has been used, for the purpose of this analysis it will

be assumed that the entire received inventory of P-32 solution is still in storage. Based on this assumption, the current activity in the possession of Immunicon is .000143 mCi or 0.143 uCi, well below the exempt quantity in the aggregate. It can also be seen that all but the last shipment in inventory has decayed to insignificant levels of activity.

III Derived Concentration Guide Level

In order to develop the DCGL for P-32, the Nuclear Regulatory Commission D and D model was run for P-32. The building occupancy scenario was used and there was no change in the default parameters. The D and D output is included as Attachment 4 to this report.

For a 1 dpm per 100 square cm surface activity, the D and D model yielded a TEDE dose of 1.92E-005 millirems. In order to reach the 25 millirem dose limit, the P-32 concentration would have to be 25 millirems divided by 1.92 E-5 millirems per dpm per 100 sq cm which yields 1.3 E+6 dpm per 100 sq cm. This is the DCGL.

The total activity on hand is 0.143 uCi, which equals 317460 dpm. This is less than the DCGL for a single 100 sq cm area. Thus if the entire inventory of P-32 were spread over a single 100 square cm area, it would be well below the DCGL for P-32. This suggests that there is no need for a comprehensive closeout survey.

NUREG 5849 Page 3.2, bottom paragraph deals with the need for a closeout survey. It states:

Consideration should be given to the amount of time that has passed since the site was in operation. Radionuclides with short half-lives may no longer be present in significant quantities, if enough time has elapsed since the site discontinued operations to allow for radioactive decay. In this case, calculations to prove that residual activity could not exceed guideline values may suffice, and surveys may not be required to demonstrate the site's radiological status, relative to license termination criteria. On the other hand, certain radionuclides, such as Th-232, may experience significant daughter product ingrowth, which must be considered in evaluating the potential residual contaminants at the time of decommissioning.

While the conditions in the above paragraph (short half life and no chance of residual activity could exceed the guideline level) Porter Consultants has performed sampling in room 162 where the radioactive material was used. This provides additional assurance of compliance and provides documentation which is designed to protect Immunicon from future liability.

The survey consists of both in-place and smear samples at 15 locations in room 162. These locations are displayed in Attachment 2, and were selected as "maximum likelihood" locations for finding any residual contamination. As can be seen in the data sheets in Attachment 1, there was no detectable presence of any radioactive material above background. All measurements were indistinguishable from normal background.

IV Instrumentation

Because only P-32 is now in use at Immunicon, only a Ludlum Model 44-9 pancake probe and Model 3 ratemeter are in use for radiation surveys. This instrument is sufficiently sensitive to detect P-32 well below the DCGL.

The meter was calibrated on January 8, 2004, so the calibration is current. The probe efficiency has been calibrated for C-14 (average beta energy 49 keV) and Si-32 (average beta energy 65 keV,) which rapidly comes into equilibrium with its short-lived daughter, P-32 (average beta energy 695 keV.) The calibration was done by JRT Calibration Services of Pottstown, PA. The Si-32 calibration indirectly calibrates the probe for P-32. The count rate observed for Si-32 betas includes both the Si-32 and P-32 betas, though it is labeled only Si-32. The probe efficiency for Si-32 betas is less than half that for the P-32 betas, so the probe efficiency given for Si-32 (counting both betas) somewhat overstates the efficiency for P-32 alone. Subtracting out the Si-32 beta at about 13% efficiency brings the probe efficiency in line with the 32 percent quoted by Ludlum.

With a 32 percent efficiency, the DCGL would produce a count rate of $1.3 \text{ E}+6$ dpm per 100 sq cm. Multiplied by 0.32 which yields $4.16 \text{ E}+5$ cpm per 100 sq cm. For in-place contamination, the 12 square cm probe area is roughly one tenth of the 100 square cm DCGL area. For smears, it may be assumed that 10 percent of the contamination is removable. In either case, the probe would yield approximately 40,000 cpm at the guideline concentration. This is easily detectable above the probe and ratemeter background.

V Previous Radiation Surveys

A) Immunicon Surveys

Routine radiation surveys were conducted on 4/27/00, 11/7/00, 12/7/00, 6/10/01, 10/3/01, 3/7/01, 10/12/01, 4/2/02, 7/20/02, 12/12/02, 3/20/02, 7/20/03 and 8/12/03. We note the dates are out of order, and suspect the survey listed as 3/20/02 was actually done on 3/12/03. Since the routine surveys supplement the surveys done after the use of radioactive material, the frequency of 13 routine surveys in three years (about four per year) seems sufficient. We note that the survey showed some I-125 contamination in the hood in the year 2000, but the results have been non-detectable from that time to the present.

Per the Radiation Safety plan, there were records of radiation surveys which were done after the use of radioactive material. In 2003, these were done on 8/11/03, 5/16/03, 4/8/03, 3/19/03, 3/20/03, 7/8/03, 4/28/03, 3/13/03, 3/17/03 and 2/11/03. There was no detectable contamination.

B) PCI Surveys

As a part of a December, 2003 audit, an additional radiation survey was performed. Area contamination (fixed plus removable) was measured using a Ludlum Pancake probe and Ludlum Model 3 ratemeter. A general sweep was conducted and nine specific locations were surveyed. No contamination above background was found in room 162, the Radiation Room. Removable contamination samples (smears) were also taken and counted at the PCI facility. No contamination above background was found.

VI Summary and Conclusions

The only radionuclide in use at the Immunicon Facility is P-32 and it was last received on 1/15/04. Decay calculations show that the inventory on hand has decayed to a quantity well below the exempt quantity for P-32. It has also been shown that the activity remaining in the facility could not cause the guideline level to be exceeded even if it were released in the room rather than being contained in its locked container.

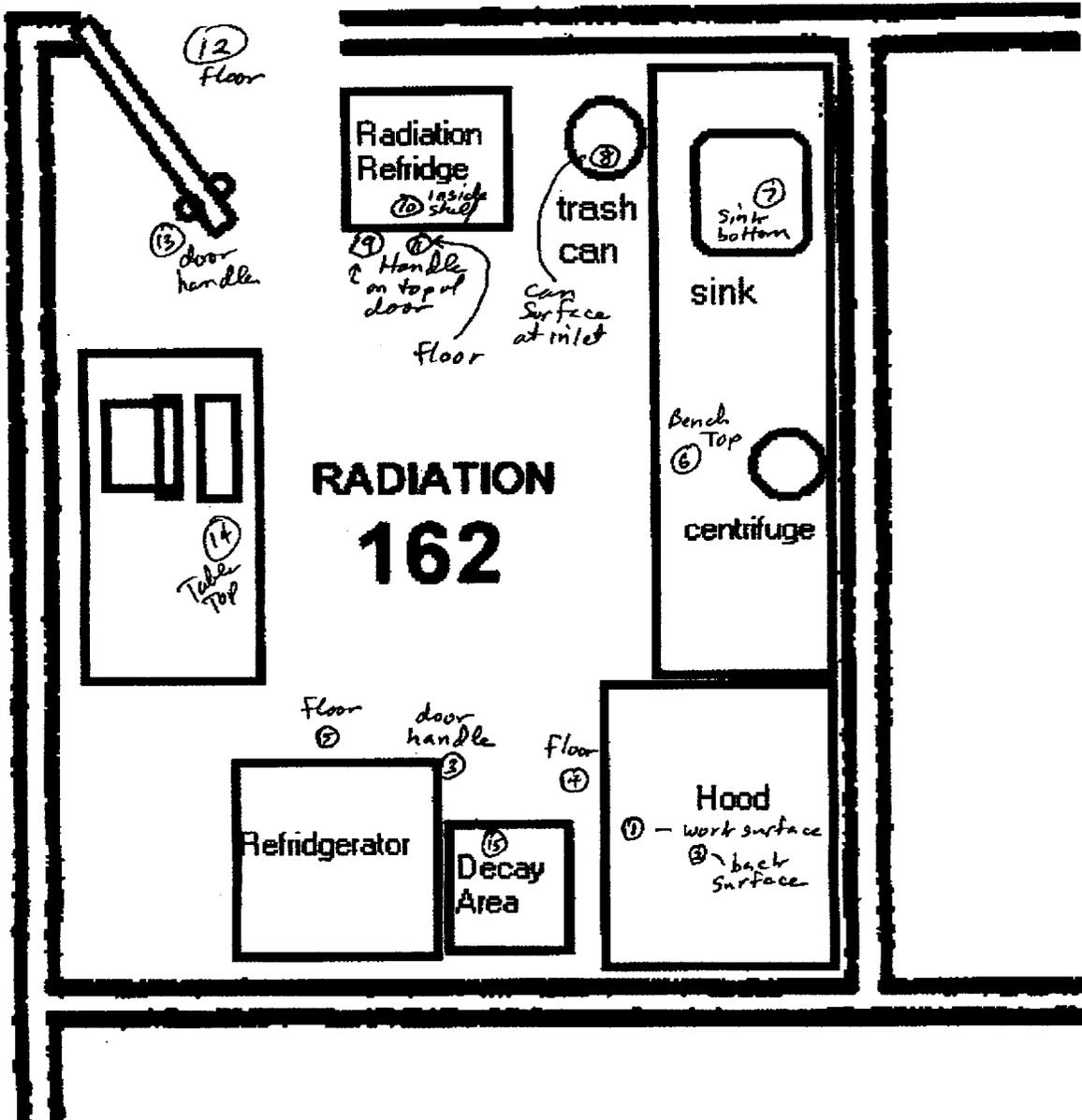
A survey of the "maximum likelihood" locations revealed no measurable radioactivity above instrument background. Porter Consultants therefore concludes that the facility meets the 25 mrem per year decommissioning criteria and can be released for unrestricted use.

Attachment 2 - Radiation Survey Locations

Note
Smears done at
all direct survey
locations in addition
to direct survey.

Immunicom Survey
6/17/04

- Radiation survey locations
- Smear locations



Attachment 3 - Current Inventory Sheets

IMMUNICON

ORIGINAL ORIGINAL ORIGINAL ORIGINAL ORIGINAL ORIGINAL ORIGINAL
Radiation Safety Policy OP 010-0005.4

Attachment 4

Radioactive Materials Receipt and Inventory Worksheet

ID/Ref date

Material Received: γ ³²P ATP (250 μCi) in 25 μL 10/31/2003

Quantity Received: 250 μCi " " "

Condition of Packaging: OK Other (Describe): _____
If package damaged, perform leak testing as determined by Radiation Safety Officer. Record Results.

Survey Results: Final Source Container: 2000 cpm Background: -50 cpm
(on yellow)

Received By: LAA/DS Date: 10/3/03 [Signature]

Date	Purpose	Quantity Used μL	Quantity Remaining μL
10/3/03	Kinase end labeling DNA		

Quantity Disposed: _____

Does Quantity Disposed + Quantities Used = Quantity Received? _____ YES _____ NO
If NO, explain below:

Material Disposal Method: _____

Material Disposed By: _____ Date: _____

Attachment 4

Radioactive Materials Receipt and Inventory Worksheet

Material Received: GAMMA 32P ATP 10µci/gl lot date 16 JAN 04

Quantity Received: 250µci

Condition of Packaging: OK Other (Describe): _____
If package damaged, perform leak testing as determined by Radiation Safety Officer. Record Results.

Survey Results: Final Source Container: 2 2060 Background: 50 cpm

Received By: Buckner Date: 1-9-04

Date	Purpose	Quantity Used µl	Quantity Remaining µl
1/15/04	end labeling	1ml	24ml
	note: End of Radioactive Material Receipt 1/9/04		
	No further materials received. WBS/Balinger 6/17/04		
	after 1/9/04. Final use of P-32 1/15/04.		

Quantity Disposed: _____

Does Quantity Disposed + Quantities Used = Quantity Received? YES NO
If NO, explain below:

Material Disposal Method: _____

Material Disposed By: _____ Date: _____

Attachment 4 - D and D Report

Program : DandD Version 1.0 Build 1.00.02

Session : test

Description :

Immunicon

Executed : 06/18/04 at 20:15:09

NRC Report

Occupancy Input Section

Execution Options

History file will be generated.

Implicit progeny doses will not be included with explicit parent.

Concentration data will be calculated.

Initial Radionuclide Activities

Chain dpm/100cm²

32P 1.0000

Code-Generated Radionuclide Activities

Chain dpm/100cm²

32P 1.0000E+000

Variable Parameters

=

No parameters have been changed.

Occupancy Output Section

Maximum Annual TEDE

This scenario started 0.00 year(s) from now
and ran for 1.00 year(s).

The peak dose of 1.92E-005 TEDE (mrem) occurred 1.00 year(s) after
license termination.

Pathway Component of
Maximum Annual Dose

Pathway	TEDE (mrem)	Percentage
External	2.30E-007	1.20
Inhalation	1.83E-005	95.77
Ingestion	5.79E-007	3.02

Total	1.92E-005	100.00

Radionuclide Component of
Maximum Annual Dose

Radionuclide	TEDE (mrem)	Percentage
32P	1.92E-005	100.00

Total	1.92E-005	100.00

References

1. Code of Federal Regulations, Title 10, Part 20
2. NUREG 1505 "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys", Nuclear Regulatory Commission,
3. NUREG-1575. "Multiagency Radiation Survey and Site Investigation Manual (MARSSIM)." Washington, D.C.: Nuclear Regulatory Commission. December 1997.
4. NUREG /CR 5512, Volumes II, III and IV, "Residual Radioactive Contamination from Decommissioning, Nuclear Regulatory Commission. May, 1999.
5. NUREG /CR 5849, "Manual for Conducting Radiological Surveys in Support of License Termination," Nuclear Regulatory Commission. June, 1992.
6. NUREG-1507 -" Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions," Nuclear Regulatory Commission., August, 1995