



Eurofins
Clinical Diagnostics

May 11, 2017

Frank P.D. Tran
Health Physicist, Materials Licensing Branch
United States Nuclear Regulatory Commission, Region III
2443 Warrenville Rd. Suite 210
Lisle, IL 60532-4352

RE: Mail Control Number 593105

Dear Mr. Tran,

In response to your letter requesting additional information related to our license termination request for NRC License No. 24-35094-01 we have addressed the eight (8) stated deficiencies in narrative form below and have attached requested documents to this letter.

- 1) Radionuclides used at our facility were limited to Hydrogen-3 and Iodine-125 as described in our Materials License, NRC Form 374 dated August 13, 2014.
- 2) A diagram of the old workspace (**Attachment 1.**) is included with this letter, as are the survey results (**Attachment 2.**). The Scintillation Counter used to analyze the samples does not provide results in disintegrations per time unit; instead results are reported in Counts per Minute (CPM). A search of the instrument literature did not reveal a formula that would convert CPM into disintegrations per time unit format.
- 3) Dr. Linda Flebbe-Rehwaldt performed the survey. Her initials appear on **Attachment 2.** as "LFR".
- 4) Survey was conducted and completed October 14, 2016. See **Attachment 2.** Instrument header information.
- 5) The instrument used to analyze the wipe samples is a Perkin-Elmer MicroBeta2 Scintillator.
- 6) The Background reading for October 14, 2016 is found on the Maintenance and Calibration Log sheet for October 2016 (**Attachment 3.**).
- 7) The Perkin-Elmer MicroBeta2 Scintillator is calibrated on an annual basis by a technician from the manufacturer. This last occurred January 27, 2016 and the technician's Field Service Report is included with this letter (**Attachment 4.**).
- 8) Receipt confirming transfer of radioactive materials and/or waste to Bionomics, Inc. may be found with this letter as **Attachment 5.**



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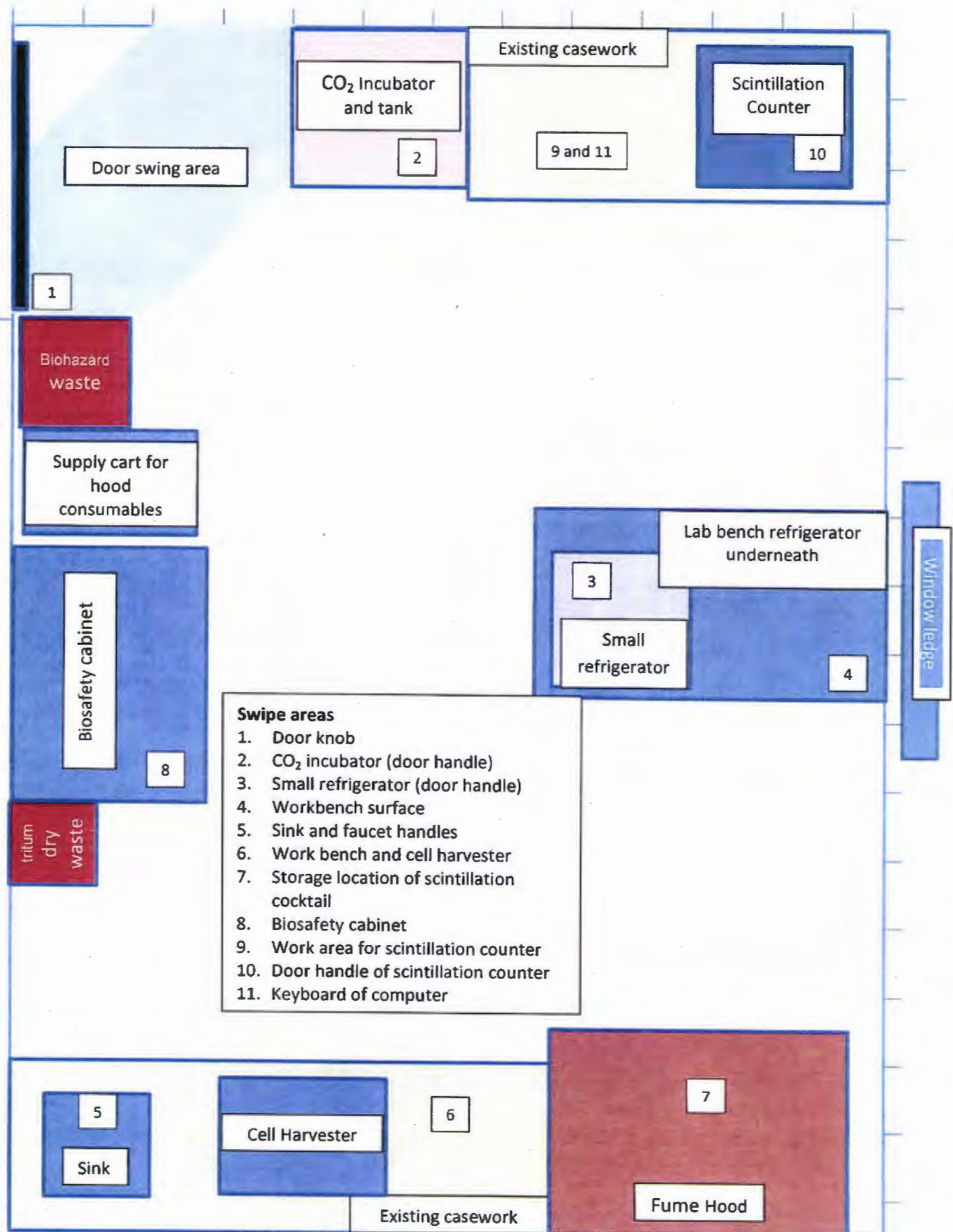
While I believe the contents of this communication address the deficiencies that you had noted, please contact me if additional information is needed to complete the requested amendment to our license.

Respectfully,

A handwritten signature in blue ink, appearing to read "MCS", written over a horizontal line.

Michael Seymour
RA/QA Manager, Chief Compliance Officer
Viracor Eurofins

Attachment 1.



Attachment 2

a030_017.txt 10/14/2016 3:45:40 PM

report printed on 10/14/2016 3:45:48 PM Page 1

C:\ProgramData\PerkinElmer\MicroBeta2\results\A030_017.txt

RUN INFORMATION:

Counting protocol no: 30
Name: Copy of Swipe test 4mL vials
Version: 1

Fri 14-Oct-2016 15:32

Detector normalization protocol no: 91
User: Irehwaldt/Linda Flebbe-Rehwaldt
MicroBeta² serial number: 49130050

COLUMNS:

SAMPLE	POS	CCPM1	CCPM1%
Unk_1	A01	43	30.5 - Door
Unk_2	A02	1506	5.2 - CO ₂ incubator recount / clean / re swipe
Unk_3	A03	43	30.5 - Refrigerator
Unk_4	A04	1628	5.0 - Work bench recount / clean + / re swipe
Unk_5	A05	44	30.2 - Sink
Unk_6	A06	30	36.5 - Harvester
Unk_7	B01	41	31.2 - Fume Hood
Unk_8	B02	28	37.8 - BSC
Unk_9	B03	23	41.7 - Scint bench
Unk_10	B04	31	35.9 - Scint counter
Unk_11	B05	40	31.6 - Scint computer
Unk_12	B06	37	32.9 - Blank
Unk_13	C01	24	40.8
Unk_14	C02	21	43.6
Unk_15	C03	18	47.1
Unk_16	C04	36	33.3
Unk_17	C05	40	31.6
Unk_18	C06	19	45.9
Unk_19	D01	14	53.5
Unk_20	D02	15	51.6
Unk_21	D03	14	53.6
Unk_22	D04	20	44.7
Unk_23	D05	41	31.2
Unk_24	D06	27	38.5

empty cassette

Total count rate: 3785.3 CCPM

*** WARNING: 10/14/2016 3:32:56 PM Calibration protocol (ID=91) for protocol (ID=30) not found, measuring without calibration data.

472
10-14-16

Microbeta login
Irehwaldt
MetalQueen II
↑
no
3p

MicroBeta²

Attachment 2

a030_018.txt 10/14/2016 3:57:54 PM

report printed on 10/14/2016 4:00:27 PM Page 1

C:\ProgramData\PerkinElmer\MicroBeta2\results\A030_018.txt
RUN INFORMATION:

Counting protocol no: 30 Fri 14-Oct-2016 15:53
Name: Copy of Swipe test 4mL vials
Version: 2
Detector normalization protocol no: 91
User: Irehwald/Linda Flebbe-Rehwaldt
MicroBeta² serial number: 49130050

COLUMNS:

SAMPLE	POS	CCPM1	CCPM1%
Unk_1	A01	24	40.8- original vial recounted } CO ₂ incubator
Unk_2	A02	39	32.0- cleaned/swiped again }
Unk_3	B01	23	41.7 }
Unk_4	B02	19	45.9 } empty
Unk_5	C01	28	37.8 original vial recounted } Bench
Unk_6	C02	35	33.8 cleaned/swiped again }
Unk_7	D01	16	50.0
Unk_8	D02	12	57.7

Total count rate: 196.5 CCPM

*** WARNING: 10/14/2016 3:53:27 PM Calibration protocol (ID=91) for protocol (ID=30) not found, measuring without calibration data.

original "hot" count was artifact
Recounted same vial + no counts - Probably
some kind of light contamination/excitation
~~Room~~ Room is clean and ready to repurpose
eelfr
10-14-16

LFR
10-14-16

MicroBeta2 Scintillator Maintenance and Calibration Log

Instrument ID: 3C-01 Month: August Oct Year: 2016
PELFR 10-14-16

DAILY MAINTENANCE																															
(Initial Date. Write N/U for dates not used.)																															
Wipe down instrument with Countoff, Contrad, or other like solution.																															
Start-Up	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Wipe Down																															

not used
10-14-16 LFN

Instrument out of service
10-14-16

MONTHLY CALIBRATION					
Perform counting protocol # 99 and read the IPA test plate. Record values obtained below.					
Date	Initial	Action	³ H	¹⁴ C	Pass/Fail
<u>10-14-16</u>	<u>LFN</u>	<u>Eff%</u>	<u>56.0999/55.7865</u>	<u>95.2785/95.1984</u>	<u>P</u>
<u>10-14-16</u>	<u>LFN</u>	<u>Bkg</u>	<u>1/1</u>	<u>2/2</u>	<u>P</u>

Monthly Calibration Acceptance Specifications


³ H		¹⁴ C	
Eff %	Bkg	Eff %	Bkg
>43%	Max 50cpm	>89	Max 60CPM

Instrument QC check Prior to final swipe test for storage +
re assignment of room.

Reviewed by: Linda Fletche Rehwaldt Title: Senior Scientist Date: 10-14-16

Attachment 3.

Attachment 4.

 PerkinElmer <i>For the Better</i>	PerkinElmer Health Sciences, Inc. 710 Bridgeport Avenue SHELTON 06484-4794 CT US Telephone : (800) 762-4000 Fax : (203) 944-4914 V.A.T Code	003
	Field Service Report	

Service Order No.	Activity Code	Desired Start Date	Model	Serial No.
312443491	PM	27-Jan-2016	MICROBETA2450-0020	SGMB49130050
Engineer Name	Work Center	Contract No.	Expiration Date	
CLARK, JOHN (VM 3976)	US03049	35378549/20	21-Feb-2016	
Customer Name/Address		Bill To Name/Address		
VIRACOR - IBT LABORATORIES INC 951 NW TECHNOLOGY DRIVE, LEES SUMMIT, MO, 64086 US		VIRACOR - IBT LABORATORIES INC, ACCOUNTS PAYABLE, 1001 NW TECHNOLOGY DR, LEES SUMMIT, MO, 64086 US		
Contact Name	Phone No.	Email Address	Customer PO No.	
FLEBBE-REHWALDT PH.D, LINDA	816-251-0203			

Time Confirmation

	Activity Type	Actual Work	Actual Start Date	Actual Start Time	Actual Finish Date	Actual Finish Time	Time Zone	Confirmation Text
x	SRV-PM Labor for Planned Servi	1.5	Feb 10, 2016	07:00:00 AM	Feb 10, 2016	08:00:00 AM	CST	Review instrument performance.
x	SRN-TV Travel - Nonbillable	6	Feb 10, 2016	08:00:00 AM	Feb 10, 2016	09:00:00 AM	CST	TRAVEL

+

Fault Coding

	Symptom Group	Symptom Code	Problem Group	Problem Code	Problem Text	Cause Group	Cause Code	Cause Text
x								

+

Clear

Material Confirmation

	Plant	Storage Location	Material	Material Description	Requirement Quantity	Requirement Quantity Unit	Unit Price	Total Price	Serial/ Batch No.
x	US12	F382			0				

+

Clear


Call Complete	Labor Hours	Travel Hours	Maintenance Performed																															
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	1.5	6	<input type="checkbox"/> Maintenance/IPV PTC Left with Customer																															
Service Engineer Signature	Date	<table border="1"> <tr> <th></th> <th>Quantity</th> <th>Unit Price</th> <th>Total</th> </tr> <tr> <td>Total Parts</td> <td></td> <td></td> <td>0</td> </tr> <tr> <td>Labor Hours</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Travel Hours</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Total</td> <td></td> <td></td> <td>0</td> </tr> <tr> <td>V.A.T at current ra</td> <td></td> <td></td> <td>0</td> </tr> <tr> <td>Total</td> <td></td> <td></td> <td>0</td> </tr> </table>						Quantity	Unit Price	Total	Total Parts			0	Labor Hours	0	0	0	Travel Hours	0	0	0	Total			0	V.A.T at current ra			0	Total			0
	Quantity	Unit Price	Total																															
Total Parts			0																															
Labor Hours	0	0	0																															
Travel Hours	0	0	0																															
Total			0																															
V.A.T at current ra			0																															
Total			0																															
Customer Signature	Date																																	
Customer Acknowledgment of receipt of the above repair/replacement.																																		
Additional Information																																		

Short description : AE-PM VISIT NEEDED

Jan 26, 2016 01:23:30 PM

 UFR
 03-09-16

Attachment 4.

 Field Service Report	PerkinElmer Health Sciences, Inc. 710 Bridgeport Avenue SHELTON 06484-4794 CT US Telephone : (800) 762-4000 Fax : (203) 944-4914 V.A.T Code	003
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Service Order No.	Activity Code	Desired Start Date	Model	Serial No.
312443491	PM	27-Jan-2016	MICROBETA2450-0020	SGMB49130050
Engineer Name	Work Center	Contract No.	Expiration Date	
CLARK, JOHN (VM 3976)	US03049	35378549/20	21-Feb-2016	
Customer Name/Address		Bill To Name/Address		
VIRACOR - IBT LABORATORIES INC 951 NW TECHNOLOGY DRIVE, LEES SUMMIT , MO, 64086 US		VIRACOR - IBT LABORATORIES INC, ACCOUNTS PAYABLE, 1001 NW TECHNOLOGY DR, LEES SUMMIT , MO, 64086 US		
Contact Name	Phone No.	Email Address	Customer PO No.	
FLEBBE-REHWALDT PH.D, LINDA	816-251-0203			

Confirmation Text
SRV-PM 1.5hrs Feb 10, 2016 07:00:00 AM Feb 10, 2016 08:00:00 AM Review instrument performance. Review error log. Perform general inspection of system. Run the IPA Normalization plate to check perform. Remove top cabinet and check mechanics, clean accordingly. Clean and lubricated linear bearing rails, if needed. Check the power supply. Check the cooling fan noise level. Clean the conveyor deck. Reinstall cover and run the IPA and check for proper operation D1, 3H=56.2% D2, 3H=55.6 D1, C14=95.4% D2, C14=95.7% SRN-TV 6hrs Feb 10, 2016 08:00:00 AM Feb 10, 2016 09:00:00 AM TRAVEI

15R-03-09-16

Estimated burden per response to comply with this information collection request: 45 minutes. This uniform manifest is required by NRC to meet reporting requirements of Federal and State Agencies for the safe transportation and disposal of low-level waste. Send comments regarding burden estimate to the Records and Privacy Service Branch (T-6 F&E), U.S. Nuclear Regulatory Commission, Washington, DC 20548-0061, or by Internet e-mail to info@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOS-10252, (2150-0154), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

FORM 540 EnergySolutions, Bear Creek Processing Operations UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST SHIPPING PAPER		5. SHIPPER - NAME AND FACILITY Vircor-IBT Laboratories 1001 NW Technology Drive Lee's Summit, MO 64086		SHIPMENT ID NUMBER 080916		7. FORM 540 AND 540A FORM 541 AND 541A FORM 542 AND 542A ADDITIONAL INFORMATION		PAGE 1 OF 1 PAGE(S) 1 PAGE(S) NONE PAGE(S) NONE PAGE(S)		8. MANIFEST NUMBER (Use this number on all continuation pages) 0816MR	
1. EMERGENCY TELEPHONE NUMBER (Include Area Code) (865) 220-8520		USER PERMIT NUMBER		SHIPMENT NUMBER 0816MR		9. GENERATOR TYPE (Specify)		9. CONSIGNEE - Name and Facility Address EnergySolutions, Bear Creek Processing Operations Operated By EnergySolutions 1550 Bear Creek Road Oak Ridge, TN 37830		CONTACT Fred Schulz TELEPHONE NUMBER (Include Area Code) (865) 481-0222	
ORGANIZATION Biometrics, Inc. Attn: Emergency Duty Officer		CONTACT Susan Oltremari		TELEPHONE NUMBER (Include Area Code) (810) 251-0259		SIGNATURE - Authorized consignee acknowledging waste receipt <i>Mike Carls</i>		DATE 09/12/16		DATE	
2. IS THIS AN "EXCLUSIVE USE" SHIPMENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST 1		6. CARRIER - Name and Address Biometrics, Inc. 1550 Bear Creek Road Oak Ridge, TN 37830		EPA ID, NUMBER TND082116493		SHIPPING DATE 08/10/2016		10. CERTIFICATION This is to certify that the herein-named materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation. This also certifies that the materials are classified, packaged, marked, and labeled and in proper condition for transportation and disposal in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulation.	
4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT? If "Yes", provide Manifest Number		EPA MANIFEST NUMBER N/A		CONTACT John McCormick		TELEPHONE NUMBER (Include Area Code) 865-220-8501		DATE 8-10-16		AUTHORIZED SIGNATURE <i>Susan Oltremari</i>	
11. U.S. DEPARTMENT OF TRANSPORTATION DESCRIPTION (Including proper shipping name, hazard class, UN ID number, and any additional information)		12. DOT LABEL "RADIOACTIVE"		13. TRANSPORT INDEX		14. PHYSICAL AND CHEMICAL FORM		15. INDIVIDUAL RADIOISOTOPES		16. TOTAL PACKAGE ACTIVITY MBq mCi	
Non-Radioactive per DOT DAW 1 - 0.05 M3 FIBER BOX		NA		NA		SOLID/OXIDES		CS-137 ; H-3		6,8080E+00 (1.8400E-01)	
										17. LSA/SCO CLASS	
										18. TOTAL WEIGHT OR VOLUME (Use appropriate units) 2.12 m ³ 20.00 m³ 10 lbs	
										19. IDENTIFICATION NUMBER OF PACKAGE VIRA-1 (16-002142)	
FOR CONSIGNEE USE ONLY				20. Generator Certification Statement							
Tennessee "License For Delivery" No. _____				A) Radioactive Materials. Certification is hereby made that this shipment of low-level radioactive waste has been prepared in accordance with a radioactive waste management program which has been approved by the Nuclear Regulatory Commission or an Agreement State regulatory agency and with the current revision of the site Material Acceptance Criteria.							
South Carolina Transport Permit No. _____				B) Hazardous Materials. Generator hereby certifies that this material does not contain a hazardous waste as defined in 40 CFR 261.							
US Ecology Generator No. _____				C) Date. Generator hereby represents and warrants that all data set forth in this UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST are true and correct to all respects and in accordance with all applicable governmental laws, rules, regulations and the Radioactive Material Licenses.							
US Ecology Permit No. _____				D) INFECTIOUS SUBSTANCE. Generator hereby certifies that this material does not contain an infectious substance as defined in 49 CFR 173.134.							
				Signature: <i>Susan Oltremari</i> <i>Susan Oltremari</i> 8/10/16							

Attachment 5.

Tran, Frank

From: Seymour, Michael <MichaelSeymour@viracor-eurofins.com>
Sent: Thursday, May 11, 2017 3:09 PM
To: Tran, Frank
Subject: [External_Sender] RE: Request for additional information regarding NRC License NO. 24-35094-01
Attachments: Response to NRC letter 4212017.pdf
Importance: High

Hello Frank,

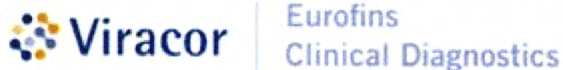
Please find attached the response to your letter dated 21 April 2017 requesting the information you also requested below. If you have any further questions or need further information, please let me know and I will insure a more prompt reply.

Thank you and kind regards,
Michael

Michael Seymour
RA/QA Manager
Chief Compliance Officer

Viracor Eurofins
1001 NW Technology Drive
Lee's Summit, MO 64086

Phone: 816 251 6654
Mobile: 816 679 2811
Email: MichaelSeymour@Viracor-Eurofins.com
Website: www.Viracor-Eurofins.com



From: Tran, Frank [mailto:Frank.Tran@nrc.gov]
Sent: Thursday, March 02, 2017 11:18 AM
To: Seymour, Michael
Subject: Request for additional information regarding NRC License NO. 24-35094-01

Dear Mr. Seymour:

We have reviewed your license termination request dated February 27, 2017. We will need the following additional information in order to complete our review and terminate your license. Please provide the following:

- a) A history of all radionuclides used at your old facility.
- b) A diagram of your old facility with survey and wipe test results keyed to specific locations. Please record your survey results using the appropriate units as described in 10 CFR 30.36 (j) (2) (i), "Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces,

and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete”.

- c) The name of the person performing the survey.
- d) The date the survey was performed.
- e) The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- f) Background readings.
- g) The date that the survey instrument was last calibrated. (Note: Your printed out survey report dated October 14, 2016, stated that the measuring were without calibration data. Please provide an explanation.)
- h) A copy of the receipt confirming that your radioactive materials and/or waste have been properly transferred to Bionomics, Inc, in Oak Ridge, Tennessee.

Please submit your response with an authorized signature as additional information to mail control 593105 by April 3, 2017. You could fax your response to 630-515-1078 or scan and email it as a pdf file to frank.tran@nrc.gov. If you have any question regarding the above, please do not hesitate to contact me at 630-829-9623 or reply to this email.

Best regards,

Frank Tran

Health Physicist/License Reviewer
NRC Region III/Division of Nuclear Materials Safety
Phone: 630-829-9623
Fax: 630-515-1078
Email: Frank.Tran@nrc.gov



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