



July 12, 2016

REC RG 1 07 14 '16 AM 08:00

Br 2

Re. License No. 06-28799-01/03032976
Control No. 590187 *Army*

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, Pa 19406-2713

Dear Sir or Madame,

This is a request to amend the above-referenced license as detailed below.

1. Condition 10: Remove 352 Knotter Drive, Cheshire CT
2. Remove Sulfur 35; Chromium 51; and Iodine 125 (i.e. items 6E, 6F, 6I respectively)

Alexion has ceased all operations at the 352 Knotter Drive facility, located in Cheshire CT. and also requests that the facility be released for unrestricted use.

In support of the amendment requests and the request for the release for unrestricted use of 352 Knotter Drive, Alexion has contracted Radiation Safety Associates, Inc. to conduct a survey following the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) and a detailed Radiological Decommissioning Report is attached that contains the results of the survey demonstrating that the levels of residual activity in the facility are acceptable.

If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Joe Paradiso, CSP
Radiation Safety Office
Director, Environmental Health and Safety
paradisoj@alxn.com

cc. Dr. S. Uden, Institutional Official

591459
NUCLEAR MATERIALS-002

**RADIOLOGICAL
DECOMMISSIONING
REPORT
ALEXION
PHARMACEUTICALS**

June 22, 2016

Jay R. Dockendorff

Radiation Safety Associates, Inc.
19 Pendleton Drive
Hebron, CT 06248
(860) 228-0487

1.0 INTRODUCTION

Alexion Pharmaceuticals is a private corporation engaging in on-going research into new pharmaceutical compounds. Alexion recently moved from a research facility in Cheshire Connecticut to New Haven Connecticut resulting in a requirement that those laboratories in Cheshire where radioactive materials were used be surveyed and released for unrestricted use.

Since its inception in September 1993, the Alexion radioactive materials laboratory has used the following isotopes: Carbon 14, Tritium, Sulphur 35, Iodine 125, Phosphorus 32 and Chromium 51.

Table 1 shows the last purchase date for the short lived isotopes and the percentage of each isotope remaining from that purchase.

Isotope	Half Life (days)	Last Purchase	Percentage remaining
Cr-51	27.704	03/28/2008	1.68E-31%
P-32	14.29	02/28/2006	2.96E-78%
I-125	60.14	08/18/1998	1.99E-31%
S-35	87.44	09/04/1997	2.16E-22%

The only isotopes that could be present as a result of activities in this laboratory would be Tritium and Carbon 14.

2.0 SITE DESCRIPTION

The Alexion Pharmaceutical facility is located at 352 Knotter Drive, in Cheshire Connecticut. All of the spaces included in this survey are located on the first floor of the building. Room D-1, also known as the hot lab was actively used for radioactive materials.

This laboratory has been used for radioactive materials since 1993. Routine Survey records were available from 1993 through January 2016 and revealed no contamination.

This survey is being conducted under the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) guidance for radiological surveys for demonstrating compliance with dose or risk-based regulations or standards.

3.0 SUMMARY OF INVESTIGATIONS

The radiological survey of this facility was performed on 22 June 2016. Based upon the history of radioactive materials use and advice from the RSO, room D-1 was presumptively designated a MARSIMM Class 2 area. Historical Site Assessment revealed no history of radioactive spills and routine surveys showed no contamination in excess of the DCGL for either isotope.

The survey consisted of a 100% scan of all floors, countertops, laboratory equipment and walls up to 2 meters with a gas proportional counter. A 1 meter square grid was superimposed on the laboratory space and a wipe was taken in every square meter of floor and countertops. Random wipes were taken on the walls up to 2 meters. Random wipes and direct measurements were taken in drawers and cabinets. Those pieces of laboratory equipment remaining in the labs were identified and had direct and wipe measurements taken. Wipes and direct measurements were taken on the inside of the fume hoods and the accessible portion of the hood vents located in room D-1. All sinks had wipes taken of the sink bowls. Drains had been previously removed due to chemical contamination. Finally, a square grid with a random start point was superimposed upon the laboratory spaces. Final status wipes and direct counts were taken at each of these grid points as well as at random locations throughout the laboratory.

Wipes taken for removable contamination were counted on a liquid scintillation counter calibrated in dual dpm mode for Tritium and Carbon 14. Measurements for total contamination were made using instruments sensitive to the low energy beta emissions of Carbon-14. All measurements were made for lengths of time sufficient to achieve the detection limit for the isotopes used in the laboratory.

Calibration certificates for the instruments used and calculations of MDA can be found in Attachment C.

No single measurement for total or removable contamination exceeded the DCGL for the isotopes of interest.

4.0 OBJECTIVES

The objective of this survey is to determine the level of contamination, if any, present in room D-1. The purpose is to provide information required to plan and execute a decontamination and decommissioning program sufficient to release the room for unrestricted use.

5.0 DERIVED CONCENTRATION GUIDELINE LEVELS (DCGLs)

Remediation goals for the final status survey will achieve the derived concentration guidelines (DCGLs) established for the area. The NRC has established a DCGL of $3.7\text{E}+06$ dpm/100cm² total contamination for Carbon 14 and a DCGL of $1.2\text{E}+08$ dpm/100cm² total contamination for Tritium. These DCGLs correspond to an exposure of 25 mrem/y. The State of Connecticut imposes a more restrictive exposure limit of 19 mrem/y which would reduce the Carbon 14 DCGL to $2.8\text{E}+06$ dpm/100cm². As the Carbon 14 DCGL is the more restrictive value it is being used as the release limit for this survey. This release limit will be applied to floors, walls and fixed assets such as laboratory benches. All of the laboratory equipment had been removed from the facility at the time of the survey.

The DCGL values are taken from Table 5.19, "Concentration (dpm/100cm²) equivalent to 25 mrem/y for the specified value of P_{crit}," published in the Federal Register on Wednesday, November 18, 1998 (FR, Vol. 63, No. 222, Notices, p.5-43 – 5-46). These DCGLs are provided by the Nuclear Regulatory Commission and correspond to an annual dose of 0.25 mSv (25 mrem) using the default parameters that are generated by the approach to be used in the new version of NRC's "DandD" program.

6.0 DATA QUALITY OBJECTIVES

As part of the DQO process the objective of the survey and the null and alternate hypotheses should be clearly stated. In demonstrating that this objective is met, the null hypothesis, H₀, tested is that residual contamination exceeds the release criterion; the alternative hypothesis, H_a, is that residual contamination meets the release criterion.

Since the beta emitting contaminants that are present in the facility are not presumed present in background, the Sign test is used to determine the number of data points needed for statistical tests. The Type I error (α) was specified as 0.05 and Type II decision error (β) was set at 0.05.

The shift, Δ , also referred to as the lower bound of the gray region (LBGR), was set as 50% of the DCGL.

The square roots of the DCGLs were taken as the standard deviation values used for calculation of the sample sizes.

These data are summarized in the following table.

	STATE of CT DCGL (dpm/100 cm ²)	Site Specific (dpm/100 cm ²)	Δ (dpm/100 cm ²)	σ (dpm/100 cm ²)	Δ/σ	Number of samples required per survey unit as per Sign Test
C-14 Total	3.7E+6	10,000	5000	100	50	14
C-14 Removable	3.7E+5	1000	500	31.62	15.81	14

Direct surveys and measurements were performed using the instruments listed in Attachment B. Using the background data from an unaffected hallway area, the background and sample count times were established to make the MDA less than the DCGL for Carbon 14.

Wipes were counted for Tritium/Carbon-14 on a liquid scintillation counter calibrated against quenched standards.

7.0 PROCEDURES - OVERVIEW

7.1 Reference Area

Background measurements were taken outside of the Class 2 area on a surface similar to that inside the survey unit but which was not subject to exposure from licensed radioactive materials. The area was an adjacent laboratory with similar materials for floors, walls, laboratory benches, drawers and cabinets.

8.0 CONCLUSIONS

Direct survey measurements from all areas sampled in the D-1 laboratory are indistinguishable from background. Wipe survey results were also indistinguishable from background. .

No direct measurement exceeds the total DCGL of $2.8\text{E}+06$ dpm/100cm² and all wipes are below the DCGL for removable contamination of $2.8\text{E}+05$ dpm/100cm².

Based upon the results of this final status survey, the average member of the critical group is unlikely to receive an annual dose of more than 19 mrem resulting from licensed radioactive material remaining at this facility.



Jay R. Dockendorff
Health Physicist

LIST OF ATTACHMENTS

- A. Instrumentation used during radiological surveys, and calibration certificates for these instruments
- B. MDA Calculations
- C. Survey Maps
- D. Survey results

ATTACHMENT A

Instrumentation

CERTIFICATE OF CALIBRATION (EXPOSURE RATE INSTRUMENT)



RSA Laboratories, Inc.

19 Pendleton Drive, P.O. Box 61
Hebron, Connecticut 06248
(860) 228-0721 Fax (860) 228-4402

Customer and Contact: **Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487**
Customer Address: **19 Pendleton Drive, Hebron, CT 06248**
Inst. Mfr. & Model: **Bicron Micro Rem LE** Inst. Type: **Survey Meter** Inst. s/n: **B768U**
Det. Mfr. & Model: **not indicated** Det. Type: **Organic Scintillator** Det. s/n: **not indicated**
Calibration Date: **13 November 2015** Due Date: **13 November 2016** Cal Interval: **1 year**

Environmental conditions: Temperature **72°F** Relative Humidity **46%** Atmospheric Pressure **29.34** inches Hg

Pre-calibration Checks:

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> Contamination survey | <input checked="" type="checkbox"/> Battery check | <input type="checkbox"/> Slow response check | |
| <input checked="" type="checkbox"/> Mechanical check | <input type="checkbox"/> Audio check | <input type="checkbox"/> Window Operation | <input type="checkbox"/> Det. Volts Vdc |
| <input checked="" type="checkbox"/> Meter zero | <input checked="" type="checkbox"/> Reset check | <input type="checkbox"/> Plateau check | |
| <input checked="" type="checkbox"/> Geotropism check | <input type="checkbox"/> Fast response check | <input type="checkbox"/> Alarm set | <input type="checkbox"/> Input sens. mV |
|
 | | | |
| <input checked="" type="checkbox"/> Pulse generator s/n 94926 | <input type="checkbox"/> Oscilloscope s/n 171-04928 | <input type="checkbox"/> Voltmeter s/n 574100002 | |

Comments:

Precision check source s/n **6** Isotope **Cs-137** Dedicated Source? ☐ Yes ☒ No
Reading #1 **2,500 µrem/h** Reading #2 **2,500 µrem/h** Reading #3 **2,500 µrem/h** Mean **2,500 µrem/h**
Precision: ☒ $\pm 10\%$ ☐ $\pm 10-20\%$ ☐ Out of tolerance

Range Multiplier	Reference Calibration Point	Instrument Indication
x 1000	154,720 µR/h	155,000 µrem/h
x 1000	49,987 µR/h	50,000 µrem/h
x 100	15,472 µR/h	15,500 µrem/h
x 100	5,951 µR/h	6,000 µrem/h
x 10	1,577 µR/h	1,600 µrem/h
x 10	595 µR/h	600 µrem/h
x 1	155 µR/h	155 µrem/h
x 1	60 µR/h	60 µrem/h
x 1	4,400 cpm @ 800 mV	155 µrem/h
x 1	1,750 cpm @ 800 mV	60 µrem/h
x 0.1	440 cpm @ 800 mV	15.5 µrem/h
x 0.1	175 cpm @ 800 mV	6 µrem/h

x 0.1 range calibrated electronically.

Sources used: ¹³⁷Cesium 750 mCi s/n KR-6244 and KR-6250, and ¹³⁷Cesium 750 µCi s/n 163.

RSA Laboratories ID# 17287. Calibration points calculated to center of detector volume unless otherwise specified. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. RSA Laboratories certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

Calibrated by: **Kurt D. Newton**

Date: **13 November 2015**

CERTIFICATE OF CALIBRATION (SCALER/RATEMETER)



RSA Laboratories, Inc.

19 Pendleton Drive, P.O. Box 61
Hebron, Connecticut 06248
(860) 228-0721 Fax (860) 228-4402

Customer and Contact: **Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487**
Customer Address: **19 Pendleton Drive, Hebron, CT 06248**
Inst. Mfr. & Model: **Ludlum Model 2224** Inst. Type: **Survey Meter** Inst. s/n: **119815**
Det. Mfr. & Model: **Ludlum 43-68** Det. Type: **Gas Proportional** Det. s/n: **091223**
Calibration Date: **21 June 2016** Due Date: **21 June 2017** Cal Interval: **1 year**

Environmental conditions: Temperature **72°F** Relative Humidity **44%** Atmospheric Pressure **29.55** inches Hg

Precalibration Checks:

<input checked="" type="checkbox"/> Contamination survey	<input checked="" type="checkbox"/> Battery check	<input type="checkbox"/> Slow response check	<input checked="" type="checkbox"/> Det. Volts 1650 Vdc
<input checked="" type="checkbox"/> Mechanical check	<input checked="" type="checkbox"/> Audio check	<input checked="" type="checkbox"/> Window Operation	
<input checked="" type="checkbox"/> Meter zero	<input checked="" type="checkbox"/> Reset check	<input type="checkbox"/> Plateau check	<input checked="" type="checkbox"/> Input sens. See comments
<input checked="" type="checkbox"/> Geotropism check	<input type="checkbox"/> Fast response check	<input type="checkbox"/> Alarm set	

☒ Pulse generator s/n 94926 ☐ Oscilloscope s/n 171-04928 ☐ Voltmeter s/n 574100002

Comments: Alpha threshold = 140 mV, Beta threshold = 3.6 mV, beta window = 3.6 - 30 mV. Th-230 efficiency measured on contact.

Precision check source s/n **6** Isotope **Cs-137** Dedicated Source? ☒ Yes ☐ No
Reading #1 **25,000 cpm** Reading #2 **25,000 cpm** Reading #3 **25,000 cpm** Mean **25,000 cpm**
Precision: ☒ $\pm < 10\%$ ☐ $\pm 10-20\%$ ☐ Out of tolerance

Range Multiplier	Reference Calibration Point	Instrument Indication
x 1000	400,000 cpm	400,000 cpm
x 1000	100,000 cpm	100,000 cpm
x 100	40,000 cpm	40,000 cpm
x 100	10,000 cpm	10,000 cpm
x 10	4,000 cpm	4,000 cpm
x 10	1,000 cpm	1,000 cpm
x 1	400 cpm	400 cpm
x 1	100 cpm	100 cpm
1 min. count	100,000 cpm	100,010 counts

All ranges calibrated electronically.

Local background (cpm) \approx alpha 2 beta 318

Range Multiplier	Cal. Source Used (isotope and s/n)	Source Activity (dpm)	Instrument Reading (cpm)		4 π Instrument Efficiency (%)	
			alpha	beta	alpha	beta
1 min. count	C-14 #4456	202,100	2	7893	0.00	3.75
1 min. count	Pm-147 #1613-32	8,253	3	1059	0.01	8.98
1 min. count	Tc-99 #D702	23,064	5	3227	0.01	12.61
1 min. count	Cs-137 #2886	13,594	3	3548	0.01	23.76
1 min. count	Cl-36 #D700	23,598	3	5733	0.00	22.95
1 min. count	Sr/Y-90 #D711	33,529	4	8644	0.01	24.83
1 min. count	Th-230 #91TH2200210	38,900	1360	6798	3.49	16.66

RSA Laboratories ID# 17797. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. Source-to-detector entry window distance for efficiency determination is 1 cm unless otherwise specified. RSA Laboratories certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

Calibrated by: **Kurt D. Newton**

Date: **21 June 2016**

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Customer and Contact: **Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487**
Customer Address: **19 Pendleton Drive, Hebron, CT 06248**
Inst. Mfr. & Model: **Ludlum Model 2224** Inst. Type: **Survey Meter** Inst. s/n: **119815**
Det. Mfr. & Model: **Ludlum 43-68** Det. Type: **Gas Proportional** Det. s/n: **091223**
Calibration Date: **21 June 2016** Due Date: **21 June 2017** Cal Interval: **1 year**

Environmental conditions: Temperature **72°F** Relative Humidity **44%** Atmospheric Pressure **29.55 inches Hg**

Pre-calibration Checks:

<input checked="" type="checkbox"/> Contamination survey	<input checked="" type="checkbox"/> Battery check	<input type="checkbox"/> Slow response check	<input checked="" type="checkbox"/> Det. Volts 1650 Vdc
<input checked="" type="checkbox"/> Mechanical check	<input checked="" type="checkbox"/> Audio check	<input checked="" type="checkbox"/> Window Operation	
<input checked="" type="checkbox"/> Meter zero	<input checked="" type="checkbox"/> Reset check	<input type="checkbox"/> Plateau check	<input checked="" type="checkbox"/> Input sens. See comments
<input checked="" type="checkbox"/> Geotropism check	<input type="checkbox"/> Fast response check	<input type="checkbox"/> Alarm set	

☒ Pulse generator s/n 94926 ☐ Oscilloscope s/n 171-04928 ☐ Voltmeter s/n 574100002

Comments: Alpha threshold \approx 140 mV, Beta threshold \approx 3.6 mV, beta window \approx 3.6 - 30 mV. All efficiencies measured on contact.

Precision check source s/n **6** Isotope **Cs-137** Dedicated Source? ☒ Yes ☐ No
Reading #1 **28,000 cpm** Reading #2 **28,000 cpm** Reading #3 **28,000 cpm** Mean **28,000 cpm**
Precision ☒ \pm 10% ☐ \pm 10-20% ☐ Out of tolerance

Range Multiplier	Reference Calibration Point	Instrument Indication
x 1000	400,000 cpm	400,000 cpm
x 1000	100,000 cpm	100,000 cpm
x 100	40,000 cpm	40,000 cpm
x 100	10,000 cpm	10,000 cpm
x 10	4,000 cpm	4,000 cpm
x 10	1,000 cpm	1,000 cpm
x 1	400 cpm	400 cpm
x 1	100 cpm	100 cpm
1 min. count	100,000 cpm	100,010 counts

All ranges calibrated electronically.

Local background (cpm) \approx alpha 2 beta 318

Range Multiplier	Cal. Source Used (isotope and s/n)	Source Activity (dpm)	Instrument Reading (cpm)		4 π Instrument Efficiency (%)	
			alpha	beta	alpha	beta
1 min. count	C-14 #4456	202,100	2	10,518	0.00	5.05
1 min. count	Pm-147 #1613-32	8,253	2	1228	0.00	11.03
1 min. count	Tc-99 #D702	23,064	1	3937	0.00	15.69
1 min. count	Cs-137 #2886	13,594	5	3753	0.02	25.27
1 min. count	Cl-36 #D700	23,598	5	6216	0.01	24.99
1 min. count	Sr/Y-90 #D711	33,529	4	9593	0.01	27.66
1 min. count	Th-230 #91TH2200210	38,900	1360	6798	3.49	16.66

RSA Laboratories ID# 17797. Instrument indicates within \pm 10% of calibration points unless otherwise indicated. Source-to-detector entry window distance for efficiency determination is 1 cm unless otherwise specified. RSA Laboratories certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

Calibrated by: **Kurt D. Newton**

Date: **21 June 2016**

CERTIFICATE OF CALIBRATION (SCALER/RATEMETER)



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Customer and Contact: **Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487**
Customer Address: **19 Pendleton Drive, Hebron, CT 06248**
Inst. Mfr. & Model: **Ludlum Model 2224** Inst. Type: **Survey Meter** Inst. s/n: **119815**
Det. Mfr. & Model: **Ludlum 43-37** Det. Type: **Gas Proportional** Det. s/n: **160827**
Calibration Date: **21 June 2016** Due Date: **21 June 2017** Cal Interval: **1 year**

Environmental conditions: Temperature **72°F** Relative Humidity **44%** Atmospheric Pressure **29.55 inches Hg**

Pre-calibration Checks:

☒ Contamination survey ☒ Battery check ☐ Slow response check
☒ Mechanical check ☒ Audio check ☒ Window Operation ☒ Det. Volts **1650 Vdc**
☒ Meter zero ☒ Reset check ☐ Plateau check
☒ Geotropism check ☐ Fast response check ☐ Alarm set ☒ Input sens. **See comments**

☒ Pulse generator s/n 94926 ☐ Oscilloscope s/n 171-04928 ☐ Voltmeter s/n 574100002

Comments: Alpha threshold \approx 140 mV, Beta threshold \approx 3.6 mV, beta window \approx 3.6 - 30 mV. Th-230 efficiency measured on contact.

Precision check source s/n **6** Isotope **Cs-137** Dedicated Source? ☒ Yes ☐ No
Reading #1 **17,000 cpm** Reading #2 **17,000 cpm** Reading #3 **17,000 cpm** Mean **17,000 cpm**
Precision: ☒ $\pm < 10\%$ ☐ $\pm 10-20\%$ ☐ Out of tolerance

Range Multiplier	Reference Calibration Point	Instrument Indication
x 1000	400,000 cpm	400,000 cpm
x 1000	100,000 cpm	100,000 cpm
x 100	40,000 cpm	40,000 cpm
x 100	10,000 cpm	10,000 cpm
x 10	4,000 cpm	4,000 cpm
x 10	1,000 cpm	1,000 cpm
x 1	400 cpm	400 cpm
x 1	100 cpm	100 cpm
1 min. count	100,000 cpm	100,010 counts

All ranges calibrated electronically.

Local background (cpm) \approx alpha 3 beta 571

Range Multiplier	Cal. Source Used (isotope and s/n)	Source Activity (dpm)	Instrument Reading (cpm)		4 π Instrument Efficiency (%)	
			alpha	beta	alpha	beta
1 min. count	C-14 #4456	202,100	6	9924	0.00	4.63
1 min. count	Pm-147 #1613-32	8,253	4	1332	0.01	9.22
1 min. count	Tc-99 #D702	23,064	4	3204	0.00	11.42
1 min. count	Cs-137 #2886	13,594	5	2490	0.01	14.12
1 min. count	Cl-36 #D700	23,598	4	3188	0.00	11.09
1 min. count	Sr/Y-90 #D711	33,529	2	4351	0.00	11.27
1 min. count	Th-230 #91TH2200210	38,900	1043	1995	2.67	3.66

RSA Laboratories ID# 17797. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. Source-to-detector entry window distance for efficiency determination is 1 cm unless otherwise specified. RSA Laboratories certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

Calibrated by: **Kurt D. Newton**

Date: **21 June 2016**

Table 1. Instrumentation for Radiological Surveys

Type of Measurement	Instrumentation		Bkgd. ^a	4 π Eff. (%)	Detection Sensitivity
	Detector	Instrument			
Surface scans and activity: Beta	Large area (584 cm ²) gas proportional, Floor monitor Ludlum, Model 43-37	Scaler/Count-rate meter ^b , Ludlum, Model 2224		4.63 (C-14)	10506.7 dpm/detector area 1799.1 dpm/100 cm ² (activity)
Surface scans and activity: Beta	Large area (126 cm ²) gas proportional, hand held monitor Ludlum, Model 43-68	Scaler/Count-rate meter ^b , Ludlum, Model 2224		5.05 (C-14)	1089.66 dpm/detector area 864.81 dpm/100 cm ² (activity)

^aNominal Values

^bMonitoring audible signal.

ATTACHMENT B

MINIMUM DETECTABLE ACTIVITY

Alexion - Direct Measurements-43-37.txt

Ludlum Model 2224 s/n 119815 w/ 43-37 s/n 160827

DETECTION LIMITS--SURFACE CONTAMINATION

INPUT DATA:

Background Count = 200 cpm

Response Time = 2 seconds

Approximate Time Constant = 0.0146667 minutes

Background and Sample Counting Time = 0.0293333 minutes

Detector Efficiency = 4.63 %

Detector Area = 584 cm²

RESULTS:

Critical Level (Lc) = 192.095 cpm above bkgd.

Detection Limit (Ld) = 486.462 cpm above bkgd.

Minimum Detectable Activity (MDA) = 10506.7 dpm/detector

Minimum Detectable Activity (MDA) = 1799.1 dpm/100 cm²

Minimum Detectable Activity (MDA) = 175.112 Bq/detector

Minimum Detectable Activity (MDA) = 0.29985 Bq/1 cm²

All values calculated to 95% CL via MARSSIM methods

Calculated by RadCalc version 1.1 on 6/30/2016 at 3:55:39 PM

Alexion - Direct Measurements.txt

Alexion - Direct Measurements

Ludlum Model 2224 s/n 119815 w/ 43-68 s/n 091223

DETECTION LIMITS--SURFACE CONTAMINATION

INPUT DATA:

Background Count = 1042 total counts

Background Counting Time = 5 minutes

Sample Counting Time = 1 minutes

Detector Efficiency = 5.05 %

Detector Area = 126 cm²

RESULTS:

Critical Level (Lc) = 26.0139 cpm above bkgd.

Detection Limit (Ld) = 55.0278 cpm above bkgd.

Minimum Detectable Activity (MDA) = 1089.66 dpm/detector

Minimum Detectable Activity (MDA) = 864.809 dpm/100 cm²

Minimum Detectable Activity (MDA) = 18.161 Bq/detector

Minimum Detectable Activity (MDA) = 0.144135 Bq/1 cm²

All values calculated to 95% CL via MARSSIM methods

calculated by RadCalc version 1.1 on 6/27/2016 at 11:58:26 AM

All values calculated to 95% CL via MARSSIM methods

For the Gas Proportional Counter 43-68 probe:

$$\frac{k_1^2 + 2 k_1 \sqrt{R_b t_s \left(1 + \frac{t_s}{t_b}\right)}}{(t_s) (E) \left(\frac{A}{100}\right) (C)}$$

where:

k_1 = one-sided confidence level factor for the chosen confidence level (95% = 1.645).
 (The MARSSIM method sets the k_1^2 term = 3.)

R_b = background count rate in cpm

t_s = sample count time in minutes

t_b = background count time in minutes

E = detector efficiency in counts per disintegration

$\frac{A}{100}$ accounts for the detector area. ($A = 126 \text{ cm}^2$.)

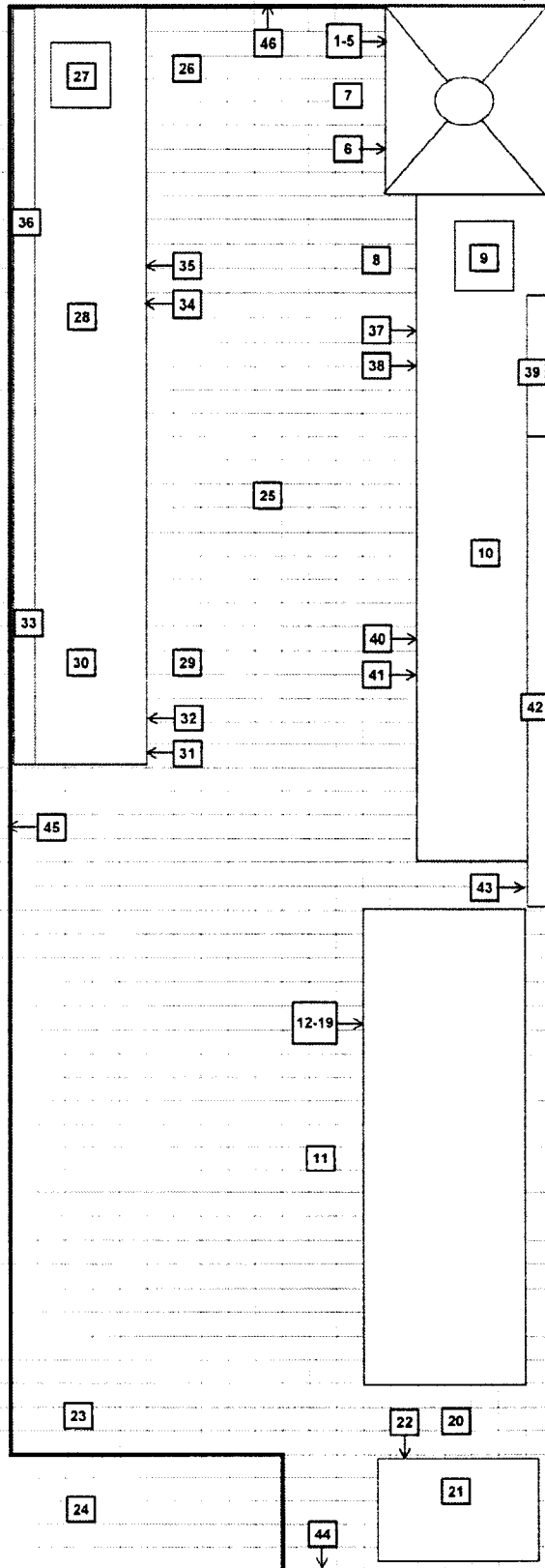
C = conversion factor from dpm to other desired activity unit, if applicable.

In this case, $C = 1$. MDA is in dpm/100 cm^2 .

$$\frac{3 + 3.29 \sqrt{(1042) (1) \left(1 + \frac{1}{5}\right)}}{(1) (0.0505) \left(\frac{126}{100}\right) (1)} = 864.81 \text{ dpm/100cm}^2 \text{ beta}$$

ATTACHMENT C

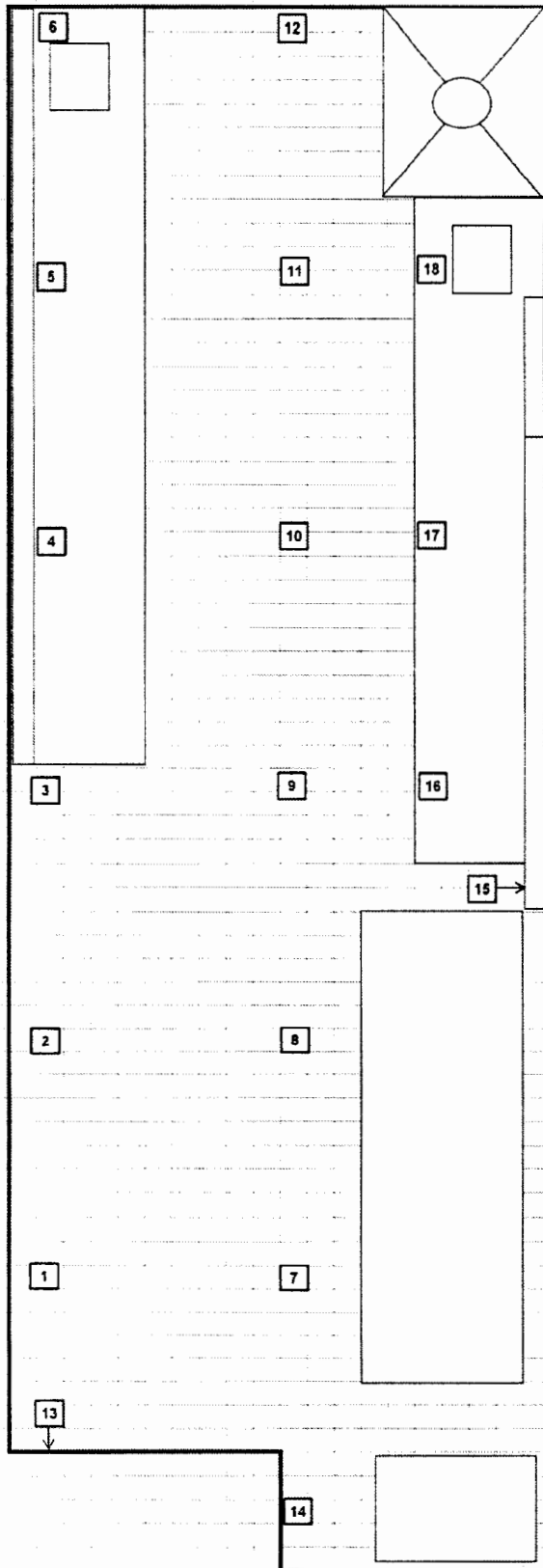
Survey Area Maps



Job: **Alexion**

Location/item: **Lab D-1 - Scoping Survey**

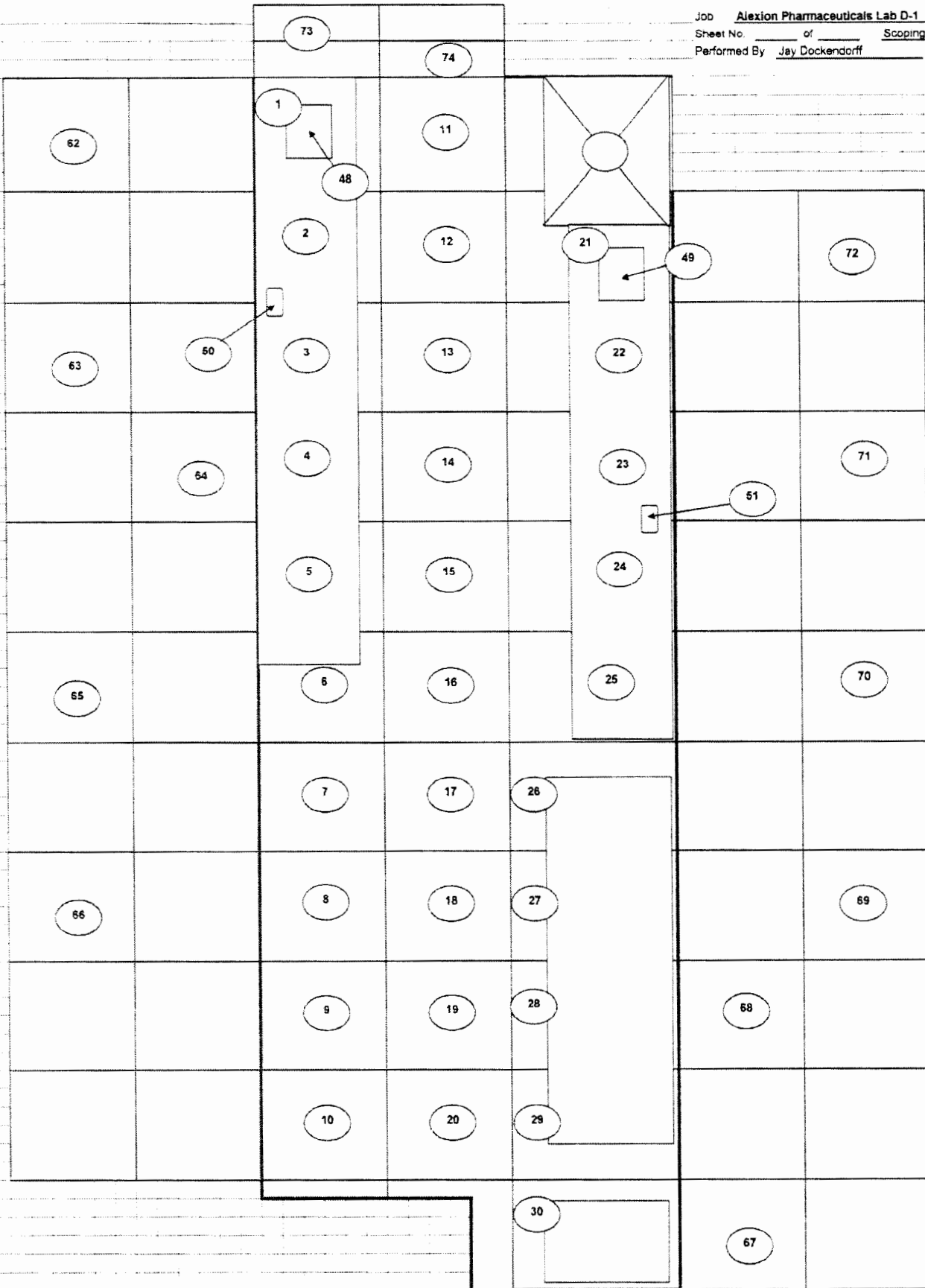
Date: **6/22/2016**



Job: **Alexion**

Location/item **Lab D-1 - Final Status Survey**

Date: **6/22/2016**



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21 Pendleton Drive

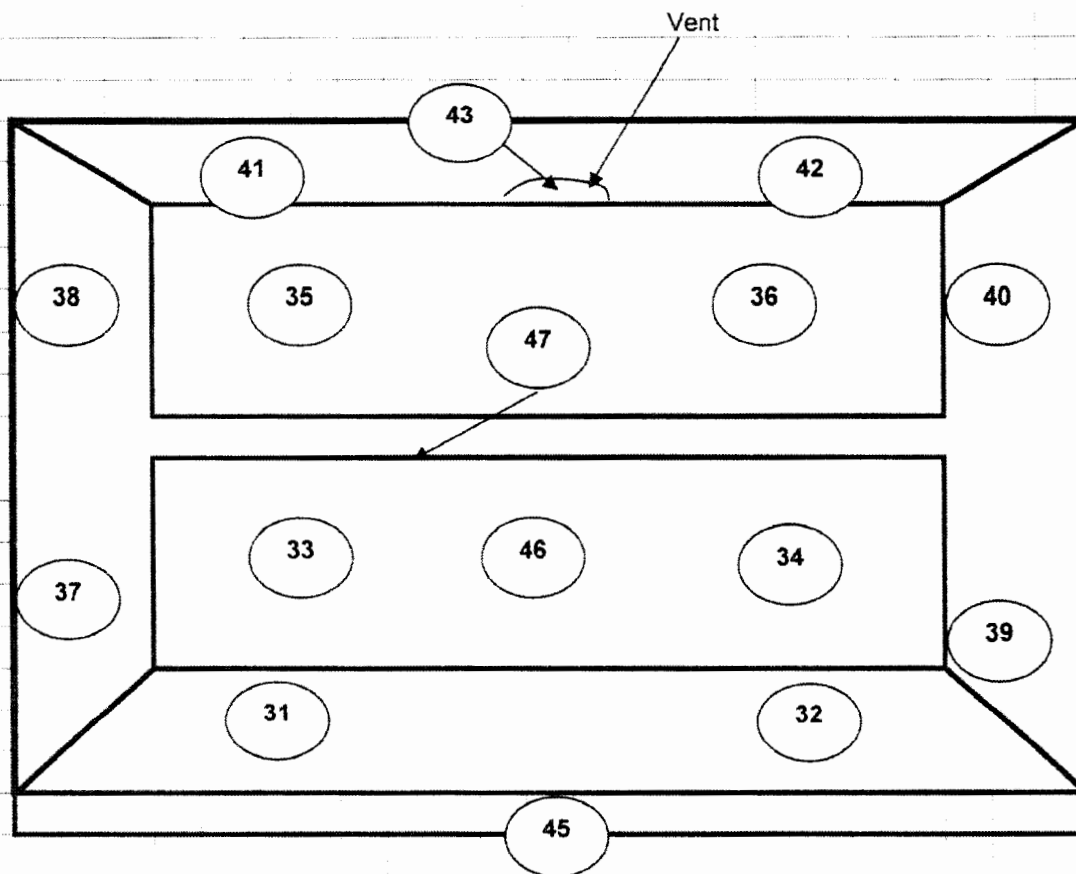
Hebron, CT 06248

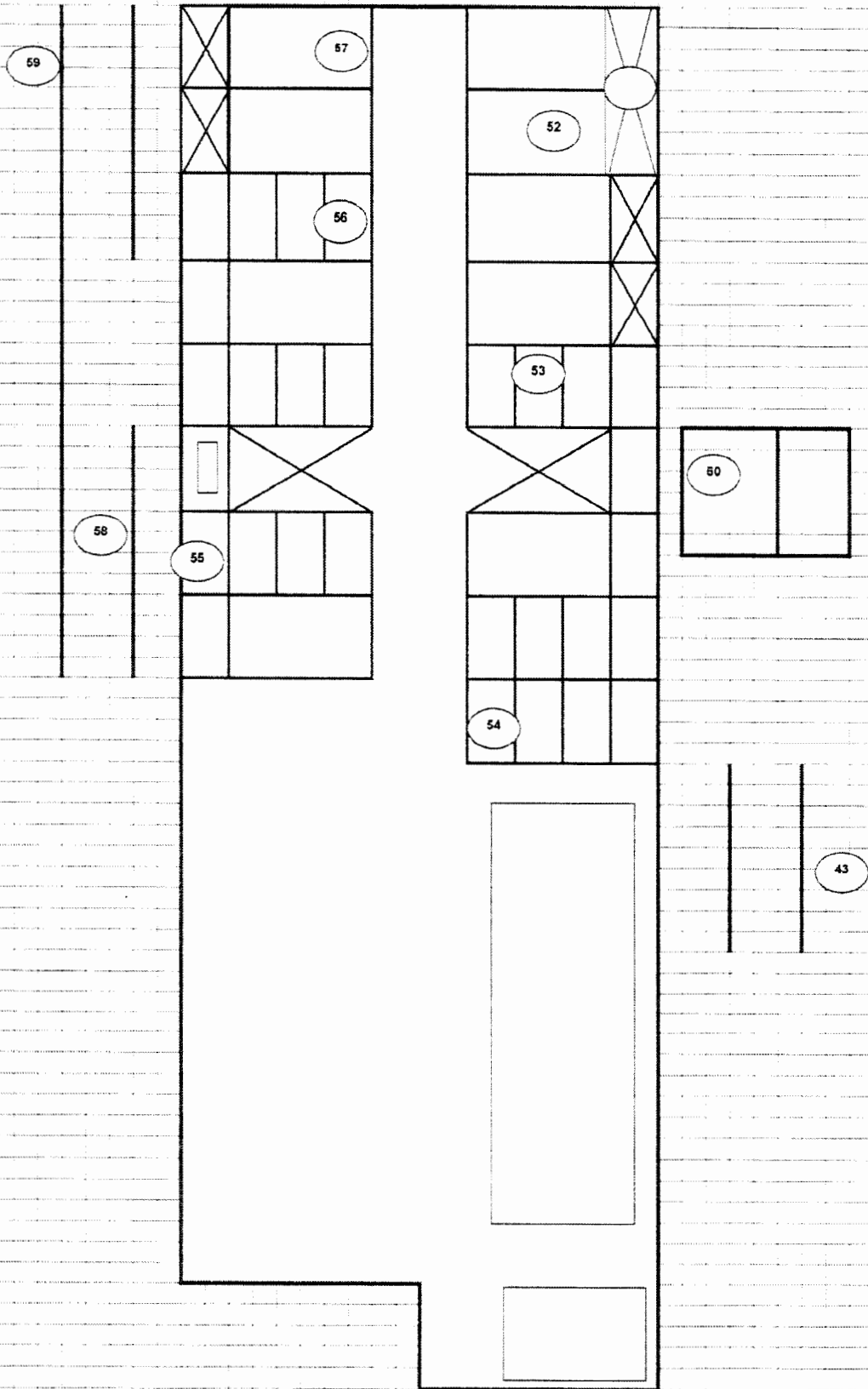
(860) 228-0721

Job Alexion Pharmaceuticals Lab D-1

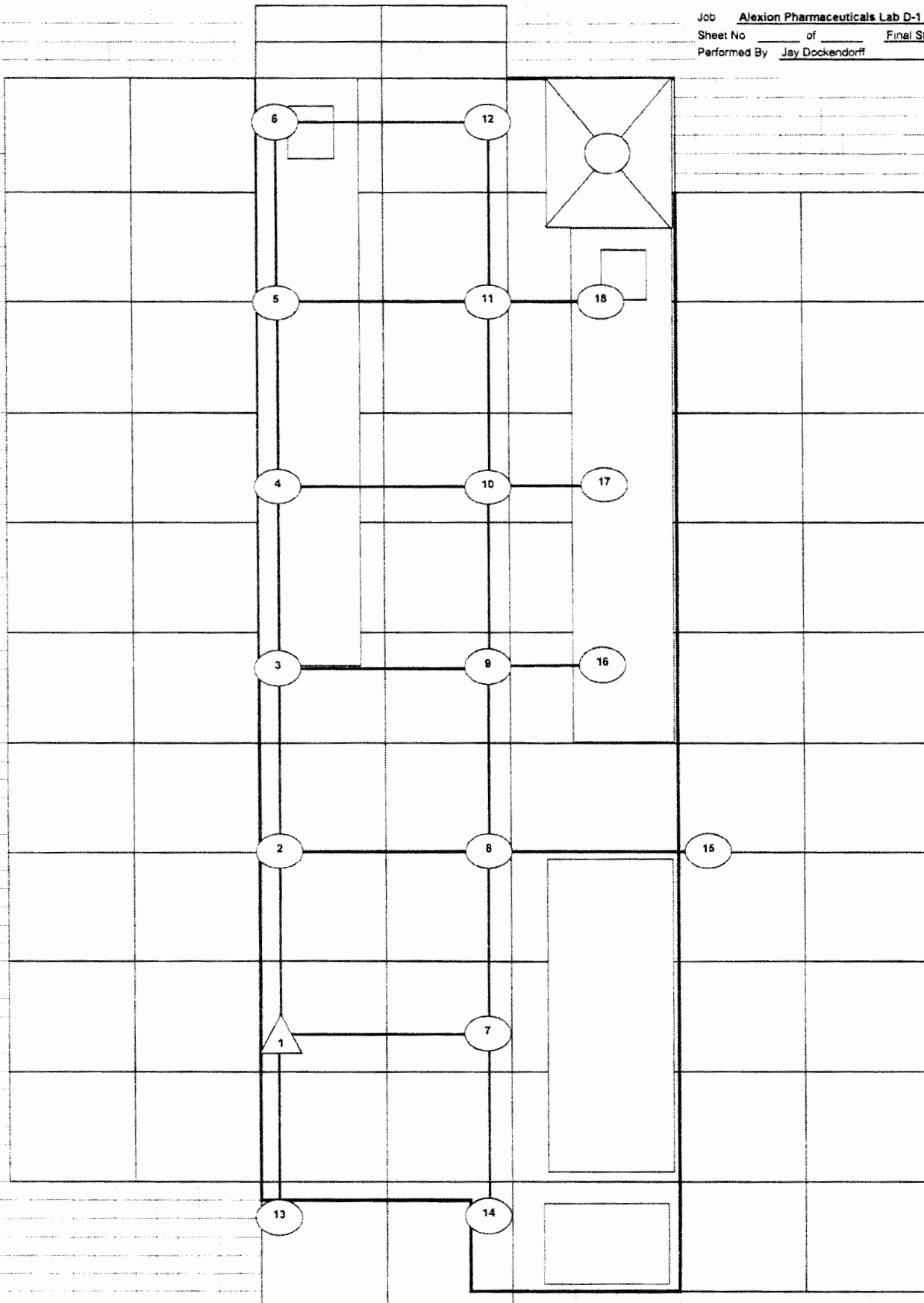
Sheet No. _____ of _____ Scoping Survey Hood

Performed By Jay Dockendorff Date 6/22/2016





Sheet No. _____ of _____ Final Status Survey Survey Wipe
Performed By Jay Dockendorff Date 6/22/2016



ATTACHMENT D

Survey Results

ATTACHMENT D

Survey Results

Alexion - Lab D-1**Final Status Survey - Direct Measurements****Date:** 6/22/2016**Instrument:** Ludlum 2224 s/n 119815 w/43-68 s/n 091223**MDA:** 865 dpm/100 cm²**C-14 efficiency (%):**

5.1

Background (5 min. count): 1042**Beta cpm:**

208

#	Location	Gross Beta cpm	Beta dpm
1	floor	223	236
2	floor	192	-251
3	floor	203	-79
4	countertop	183	-393
5	countertop	180	-440
6	countertop	192	-251
7	floor	237	456
8	floor	229	330
9	floor	234	409
10	floor	207	-16
11	floor	229	330
12	floor	192	-251
13	wall	206	-31
14	floor	193	-236
15	wall	238	471
16	countertop	185	-361
17	countertop	223	236
18	countertop	203	-79

Alexion - Lab D-1
Scoping Survey - Direct Measurements
Date: 6/22/2016

Instrument: Ludlum 2224 s/n 119815 w/43-68 s/n 091223

MDA: 865 dpm/100 cm²

C-14 efficiency (%):

Background (5 min. count): 1042

Beta cpm: 5.1
Beta dpm: 208

#	Location	Gross Beta cpm	Beta dpm
1	hood - base	197	-173
2	hood - left wall	217	141
3	hood - right wall	184	-377
4	hood - back wall	222	220
5	hood - upper back wall	201	-110
6	hood - cabinet	223	236
7	floor	192	-251
8	floor	232	377
9	sink	213	79
10	countertop	223	236
11	floor	237	456
12	air hood - base left	211	47
13	air hood - base right	232	377
14	air hood - left wall	192	-251
15	air hood - right wall	211	47
16	air hood - back wall left	201	-110
17	air hood - back wall right	207	-16
18	air hood - ceiling left	202	-94
19	air hood - ceiling right	206	-31
20	floor	193	-236
21	LSC - outside	231	361
22	LSC - inside	207	-16
23	floor	223	236
24	floor - hallway	224	251
25	floor	234	409
26	floor	194	-220
27	sink	225	267
28	countertop	180	-440
29	floor	207	-16
30	countertop	183	-393
31	cabinet	217	141
32	drawer	203	-79
33	shelf	197	-173
34	cabinet	205	-47
35	drawer	192	-251
36	shelf	199	-141
37	cabinet	233	393
38	drawer	205	-47
39	wall cabinet	222	220
40	cabinet	234	409
41	drawer	193	-236
42	shelf	219	173
43	wall	238	471
44	wall	195	-204
45	wall	205	-47
46	wall	211	47

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Report No. **Report 1**

Customer: **Alexion Pharmaceuticals**

Customer Samp No. **N/A**

Location: **352 Knotter Drive, Cheshire, CT**

RSA Lab Sample No. **36998**

Project: **Lab Decommissioning**

Date Collected: **6/22/2016**

Samp. Description: **Wipes**

Date Counted: **6/22/2016**

Matrix: **Wipes**

H-3 LLD dpm= 76.81

H-3 QC = 145099 +/- 14510 dpm

C-14 LLD dpm= 48.66

C-14 QC= 134800 +/- 13480 dpm

RSA ID#	CUST. ID#	Location	H-3 CPM	H-3 DPM	C-14 CPM	C-14 DPM	HE Beta CPM	
BG		BACKGROUND	7.40		21.60		10.20	
36998-1	1	Counter Top	0.00	0	0.00	0.00	4.80	
36998-2	2	Counter Top	5.69	26.46	0.00	0.00	1.80	
36998-3	3	Counter Top	4.83	22.39	0.00	0.00	2.80	
36998-4	4	Counter Top	2.24	0.00	12.19	17.23	1.80	
36998-5	5	Counter Top	1.38	3.44	2.36	3.29	0.00	
36998-6	6	Floor	0.00	0.00	8.26	11.73	2.80	
36998-7	7	C-11 Object 7	2.24	0.00	9.24	13.03	0.00	
36998-8	8	C-11 Object 8	3.10	4.04	8.26	11.64	1.80	
36998-9	9	C-11 Object 9	1.38	0.95	4.33	6.11	11.80	
36998-10	10	C-11 Object 10	0.52	2.44	0.00	0.00	0.00	
36998-11	11	C-11 Object 11	3.10	0	11.21	15.93	0.00	
36998-12	12	C-11 Object 12	3.96	15.76	2.36	3.22	0.00	
36998-13	13	C-11 Object 13	0.00	0.00	5.31	7.61	2.80	
36998-14	14	C-11 Object 14	3.10	14.43	0.00	0.00	0.00	
36998-15	15	Floor	0.00	0.00	0.00	0.00	1.80	
36998-16	16	C-11 Object 16	0.00	0.00	0.00	0.00	5.80	
36998-17	17	C-9 Object 17	6.55	30.61	0.00	0.00	0.00	
36998-18	18	C-9 Object 18	0.52	2.41	0.00	0.00	0.00	
36998-19	19	C-9 Object 19 Right	0.00	0.00	2.36	3.35	10.80	
36998-20	20	C-9 Object 19 Left	1.38	6.50	0.00	0.00	0.00	
36998-21	21	Counter Top	3.96	18.43	0.00	0.00	0.00	
36998-22	22	Counter Top	0.52	0.00	2.36	3.32	4.80	
36998-23	23	Counter Top	0.00	0.00	0.00	0.00	3.80	
QC H-3	QC H-3	QC H-3	14717.10	101254.00	634.65	292.76	3.80	
36998-24	24	Counter Top	0.52	0.00	4.33	6.13	0.80	
36998-25	25	Counter Top	4.38	18.31	3.34	4.57	0.00	
36998-26	26	Floor	0.00	0.00	7.28	10.35	3.80	
36998-27	27	Floor	0.00	0.00	5.31	7.56	0.00	
36998-28	28	Floor	3.96	3.03	12.19	17.25	0.80	
36998-29	29	Floor	0.00	0.00	0.39	0.56	0.80	
36998-30	30	Floor	0.00	0.00	9.24	13.17	7.80	
36998-31	31	Hood Counter Top L	3.10	14.29	0.00	0.00	0.00	
36998-32	32	Hood Counter Top R	1.38	6.37	0.00	0.00	0.00	
36998-33	33	Hood Back Low L	0.00	0.00	8.26	11.68	7.80	
36998-34	34	Hood Back Low R	0.52	2.39	0.00	0.00	3.80	

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RSA ID#	CUST. ID#	LOCATION	H-3 CPM	H-3 DPM	C-14 CPM	C-14 DPM	HE Beta CPM	HE Beta DPM
36998-35	35	Hood Back high L	1.38	2	3.34	4.68	1.80	
36998-36	36	Hood Back high R	0.52	2.41	0.00	0.00	0.00	
36998-37	37	Hood Side Low L	4.38	0.00	20.06	28.33	0.00	
36998-38	38	Hood Side High L	5.69	0.00	21.04	29.66	1.80	
36998-39	39	Hood Side Low R	0.52	0.00	6.29	8.93	7.80	
36998-40	40	Hood Side High R	5.69	20.15	5.31	7.38	3.80	
36998-41	41	Vent Shield L	1.38	0.00	12.19	17.34	2.80	
36998-42	42	Vent Shield R	0.00	0.00	8.26	11.81	6.80	
36998-43	43	Vent tube - hood	3.96	4.37	11.21	15.76	1.80	
36998-44	44	NOT USED-BLANK	5.69	18.56	6.29	8.72	3.80	
36998-45	45	Hood Sill	4.83	13.30	7.28	10.14	8.80	
36998-46	46	Hood glass - back	1.38	0.00	12.19	17.24	0.00	
QC C-14	QC C-14	QC C-14	21263.20	0.00	82126.50	127666.00	21.80	
36998-47	47	Back of hood back panel	0.52	0.00	7.28	10.41	0.00	
36998-48	48	Sink 1	10.86	46.26	3.34	4.36	8.80	
36998-49	49	Sink 2	7.41	31.40	2.36	3.09	0.00	
36998-50	50	Sink 3	0.52	2.41	0.00	0.00	0.80	
36998-51	51	Sink 4	6.55	31.09	0.00	0.00	3.80	
36998-52	52	Cabinet under Hood	2.24	3.75	531.00	5.31	4.80	
36998-53	53	Drawer	7.41	32.68	1.38	1.38	2.80	
36998-54	54	Drawer	0.52	0.00	8.26	8.26	3.80	
36998-55	55	Drawer	2.24	8.65	1.38	1.38	4.80	
36998-56	56	Drawer	0.00	0.00	0.00	0.00	6.80	
36998-57	57	Cabinet	0.52	0.00	2.36	2.36	1.80	
36998-58	58	Shelf	0.52	2.40	0.00	0.00	4.80	
36998-59	59	Shelf	3.96	16.67	1.38	1.38	5.80	
36998-60	60	Wall cabinet shelf	7.41	22.94	9.24	9.24	1.80	
36998-61	61	Shelf	1.38	7.64	0.00	0.00	3.80	
36998-62	62	Wall 2M	7.41	34.21	0.00	0.00	4.80	
36998-63	63	Wall 2M	2.24	7.44	2.36	2.36	4.80	
36998-64	64	Wall 1M	0.00	0.00	0.00	0.00	2.80	
36998-65	65	Wall 2M	0.52	0.68	1.38	1.38	0.00	
36998-66	66	Wall 2M	3.96	1.90	13.18	13.18	1.80	
36998-67	67	Wall 1M	0.00	0.00	0.00	0.00	0.00	
36998-68	68	Wall 1M	0.00	0.00	2.36	2.36	0.00	
36998-69	69	Wall 2M	10.00	46.44	0.00	0.00	0.00	
QC BL	QC BL	QC BL	0.00	0.00	0.00	0.00	0.00	
36998-70	70	Wall 2M	2.24	10.40	0.00	0.00	0.00	
36998-71	71	Wall 2M	0.00	0.00	0.00	0.00	1.80	
36998-72	72	Wall 2M	5.69	26.32	0.00	0.00	4.80	
36998-73	73	Wall 2M	1.38	6.39	0.00	0.00	6.80	
36998-74	74	Wall 1M	3.10	4.08	8.26	11.58	1.80	
36998-75	75	Free standing hood counter L	3.10	2.83	9.24	13.00	2.80	
36998-76	76	Free standing hood counter R	3.96	18.03	0.39	0.42	7.80	
36998-77	77	Free standing hood back L	1.38	0.95	4.33	6.11	0.00	
36998-78	78	Free standing hood back R	0.52	0.00	8.26	11.74	0.00	
36998-79	79	Free standing hood side L	7.41	20.37	11.21	15.62	0.80	

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C-14 LLD dpm= 48.66

[illegible]

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Report No. **Report 1**

Customer: **Alexion Pharmaceuticals**

Customer Samp No. **N/A**

Location: **352 Knotter Drive, Cheshire, CT**

RSA Lab Sample No. **30409**

Project: **Lab Decommissioning**

Date Collected: **6/22/2016**

Samp. Description: **Wipes**

Date Counted: **6/22/2016**

Matrix: **Wipes**

H-3 LLD dpm= 75.08

C-14 LLD dpm= 48.66

RSA ID#	CUST. ID#	Location	H-3 CPM	H-3 DPM	C-14 CPM	C-14 DPM	HE Beta CPM	
BG		BACKGROUND	7.00		21.60		10.20	
36998-1	1	Counter Top	0.00	0	0.00	0.00	4.80	
36998-2	2	Counter Top	5.69	26.46	0.00	0.00	1.80	
36998-3	3	Counter Top	4.83	22.39	0.00	0.00	2.80	
36998-4	4	Counter Top	2.24	0.00	12.19	17.23	1.80	
36998-5	5	Counter Top	1.38	3.44	2.36	3.29	0.00	
36998-6	6	Floor	0.00	0.00	8.26	11.73	2.80	
36998-7	7	C-11 Object 7	2.24	0.00	9.24	13.03	0.00	
36998-8	8	C-11 Object 8	3.10	4.04	8.26	11.64	1.80	
36998-9	9	C-11 Object 9	1.38	0.95	4.33	6.11	11.80	
36998-10	10	C-11 Object 10	0.52	2.44	0.00	0.00	0.00	
36998-11	11	C-11 Object 11	3.10	0	11.21	15.93	0.00	
36998-12	12	C-11 Object 12	3.96	15.76	2.36	3.22	0.00	
36998-13	13	C-11 Object 13	0.00	0.00	5.31	7.61	2.80	
36998-14	14	C-11 Object 14	3.10	14.43	0.00	0.00	0.00	
36998-15	15	Floor	0.00	0.00	0.00	0.00	1.80	
36998-16	16	C-11 Object 16	0.00	0.00	0.00	0.00	5.80	
36998-17	17	C-9 Object 17	6.55	30.61	0.00	0.00	0.00	
36998-18	18	C-9 Object 18	0.52	2.41	0.00	0.00	0.00	
36998-19	19	C-9 Object 19 Right	0.00	0.00	2.36	3.35	10.80	
36998-20	20	C-9 Object 19 Left	1.38	6.50	0.00	0.00	0.00	
36998-21	21	Counter Top	3.96	18.43	0.00	0.00	0.00	
36998-22	22	Counter Top	0.52	0.00	2.36	3.32	4.80	
36998-23	23	Counter Top	0.00	0.00	0.00	0.00	3.80	
QC H-3	QC H-3	QC H-3	14717.10	101254.0	634.65	292.76	3.80	
36998-24	24	Counter Top	0.52	0.00	4.33	6.13	0.80	
36998-25	25	Counter Top	4.38	18.31	3.34	4.57	0.00	
36998-26	26	Floor	0.00	0.00	7.28	10.35	3.80	
36998-27	27	Floor	0.00	0.00	5.31	7.56	0.00	
36998-28	28	Floor	3.96	3.03	12.19	17.25	0.80	
36998-29	29	Floor	0.00	0.00	0.39	0.56	0.80	
36998-30	30	Floor	0.00	0.00	9.24	13.17	7.80	
36998-31	31	Hood Counter Top L	3.10	14.29	0.00	0.00	0.00	
36998-32	32	Hood Counter Top R	1.38	6.37	0.00	0.00	0.00	
36998-33	33	Hood Back Low L	0.00	0.00	8.26	11.68	7.80	
36998-34	34	Hood Back Low R	0.52	2.39	0.00	0.00	3.80	

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RSA ID#	CUST. ID#	LOCATION	H-3 CPM	H-3 DPM	C-14 CPM	C-14 DPM	HE Beta CPM	HE Beta DPM
36998-35	35	Hood Back high L	1.38	2	3.34	4.68	1.80	
36998-36	36	Hood Back high R	0.52	2.41	0.00	0.00	0.00	
36998-37	37	Hood Side Low L	4.38	0.00	20.06	28.33	0.00	
36998-38	38	Hood Side High L	5.69	0.00	21.04	29.66	1.80	
36998-39	39	Hood Side Low R	0.52	0.00	6.29	8.93	7.80	
36998-40	40	Hood Side High R	5.69	20.15	5.31	7.38	3.80	
36998-41	41	Vent Shield L	1.38	0.00	12.19	17.34	2.80	
36998-42	42	Vent Shield R	0.00	0.00	8.26	11.81	6.80	
36998-43	43	Vent tube - hood	3.96	4.37	11.21	15.76	1.80	
36998-44	44	NOT USED-BLANK	5.69	18.56	6.29	8.72	3.80	
36998-45	45	Hood Sill	4.83	13.30	7.28	10.14	8.80	
36998-46	46	Hood glass - back	1.38	0.00	12.19	17.24	0.00	
QC C-14	QC C-14	QC C-14	21263.20	0.00	82126.50	127666.00	21.80	
36998-47	47	Back of hood back panel	0.52	0.00	7.28	10.41	0.00	
36998-48	48	Sink 1	10.86	46.26	3.34	4.36	8.80	
36998-49	49	Sink 2	7.41	31.40	2.36	3.09	0.00	
36998-50	50	Sink 3	0.52	2.41	0.00	0.00	0.80	
36998-51	51	Sink 4	6.55	31.09	0.00	0.00	3.80	
36998-52	52	Cabinet under Hood	2.24	3.75	531.00	5.31	4.80	
36998-53	53	Drawer	7.41	32.68	1.38	1.38	2.80	
36998-54	54	Drawer	0.52	0.00	8.26	8.26	3.80	
36998-55	55	Drawer	2.24	8.65	1.38	1.38	4.80	
36998-56	56	Drawer	0.00	0.00	0.00	0.00	6.80	
36998-57	57	Cabinet	0.52	0.00	2.36	2.36	1.80	
36998-58	58	Shelf	0.52	2.40	0.00	0.00	4.80	
36998-59	59	Shelf	3.96	16.67	1.38	1.38	5.80	
36998-60	60	Wall cabinet shelf	7.41	22.94	9.24	9.24	1.80	
36998-61	61	Shelf	1.38	7.64	0.00	0.00	3.80	
36998-62	62	Wall 2M	7.41	34.21	0.00	0.00	4.80	
36998-63	63	Wall 2M	2.24	7.44	2.36	2.36	4.80	
36998-64	64	Wall 1M	0.00	0.00	0.00	0.00	2.80	
36998-65	65	Wall 2M	0.52	0.68	1.38	1.38	0.00	
36998-66	66	Wall 2M	3.96	1.90	13.18	13.18	1.80	
36998-67	67	Wall 1M	0.00	0.00	0.00	0.00	0.00	
36998-68	68	Wall 1M	0.00	0.00	2.36	2.36	0.00	
36998-69	69	Wall 2M	10.00	46.44	0.00	0.00	0.00	
QC BL	QC BL	QC BL	0.00	0.00	0.00	0.00	0.00	
36998-70	70	Wall 2M	2.24	10.40	0.00	0.00	0.00	
36998-71	71	Wall 2M	0.00	0.00	0.00	0.00	1.80	
36998-72	72	Wall 2M	5.69	26.32	0.00	0.00	4.80	
36998-73	73	Wall 2M	1.38	6.39	0.00	0.00	6.80	
36998-74	74	Wall 1M	3.10	4.08	8.26	11.58	1.80	
36998-75	75	Free standing hood counter L	3.10	2.83	9.24	13.00	2.80	
36998-76	76	Free standing hood counter R	3.96	18.03	0.39	0.42	7.80	
36998-77	77	Free standing hood back L	1.38	0.95	4.33	6.11	0.00	
36998-78	78	Free standing hood back R	0.52	0.00	8.26	11.74	0.00	
36998-79	79	Free standing hood side L	7.41	20.37	11.21	15.62	0.80	

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ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Alexion Pharmaceuticals, Inc.
ATTN: Stephen Vden, M.D., Senior VP, Research
100 College Street
New Haven, CT 06511

Date

July 20, 2016

License Number(s)

06-28799-01

Mail Control Number(s)

591459

Licensing and/or Technical Reviewer or Branch

Commercial, Industrial, R&D, and Academic Branch
(Branch 2)

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 07/12/2016

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239