



FOOD AND DRUG ADMINISTRATION  
109 Holton Street  
Winchester, Massachusetts

Mr. Dennis Lawyer  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

J-6

Date: February 5, 2016

Docket No. 03004675  
License No. 20-08361-01  
Control No. 583771 (Referance) RLJ

Subject: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR LICENSE AMENDMENT.

Dear Mr. Lawyer:

This Memorandum is in reply to our conversation with on Monday February 1, 2016.

(1.) Our San Francisco Facility (1431 Harbor Bay Parkway, Alameda, CA) returned its NITON detector to the Company. The NITON detector contained the following radionuclides – Cadmium-109 and AM-241 Solid Sources. When It was returned, the Cd-109 was inadvertently left out of our request in the Amendment after we returned our NITON Instrument (XLP 300 Series Analyzer) to the Thermo Electron Corporation. It also contained an Americium-241 source which was deleted from our License at that time from our request for the Amendment. Attached is the final swipe of the NITON, prior to its being shipped to Thermo.

(2.) We would also like to delete our Atlanta, GA Facility from our NRC License as they no longer possess any reportable Nickel-63 Detectors. The report on the decommissioning of the Facility was forwarded to your Inspector at our last inspection, at his request. However I have attached the final results.

(3.) In addition our Denver Facility should also be deleted. The remaining radionuclides i.e. Carbon-14, Tritium, Cesium-137 Source and Nickel-63 were recently removed. Tritium was an 'exempt solution' was used in the CHARM analysis. The Nickel-63 sources for the past 10 years of swipes showed no detectable activity.

(4) The FDA Facility at 158-15 Liberty Avenue, Jamaica, NY – please reduce the activity from 100 millicuries to 0.5 millicuries for Tritium. The address '158-15' is commonly used type in NY

Should you have any questions regarding this Amendment, please contact me:  
781-799-7838

Sincerely,

Ed. Baratta, Radiation Safety Officer, HHS/FDA/NER/WEAC

589945

STDS (µCi) AT CAL. DATE  
 STD B                    STD 0.1  
 6.50E-03                1.40E-03  
 DATE: 01/07/99

NDA = 2 X BACKGROUND - No action needed  
 NDA = > 3 - 5X BACKGROUND  
 NDA = greater than 5X BACKGROUND = observe and monitor  
 NEGATIVE ACTIVITY ENTERED AS ZERO

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	VIAL	COUNT DATE	Length of Count (min.)	GROSS CPM	BLANK CPM	NET CPM CALC.	NET CPM	GROSS STD(B+0.1) CPM	NET CPM STD(B+0.1)	EFF. CALC.	EFF.	ACTIVITY CALC. (nCi/swipe)	z-sigma ACTIVITY UNCERTAINTY (nCi/swipe)
2011																	

San Francisco	5192	08/19/11	Niton		7	08/25/11	5.00	23.51	25.26	-1.75	-1.75	8394.41	8394.41	0.522	0.522	-0.002	0.048
San Francisco	1499	08/19/11	Niton		8	08/25/11	5.00	26.20	25.26	0.94	0.94	8394.41	8394.41	0.522	0.522	0.001	0.048
BLK	BLK	08/25/11	BLK	BLK	9	08/25/11	5.00	25.26	25.26	0.00	0.00	8394.41	8394.41	0.522	0.522	0.000	0.048
STD B 0.1	STD	07/26/11	STD	STD	10	08/25/11	5.00	1128.27	25.26	1103.01	1103.01	8394.41	8394.41	0.522	0.522	0.950	0.105
STD A 0.5	STD	07/26/11	STD	STD	11	08/25/11	5.00	7266.14	25.26	7240.88	7240.88	8394.41	8394.41	0.522	0.522	6.240	0.167

STDS (μCi) AT CAL. DATE	
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2011							

San Francisco	5192	08/19/11	Niton		0.01	No action	
San Francisco	1499	08/19/11	Niton		0.01	No action	
BLK	BLK	08/25/11	BLK	BLK	0.01	No action	
STD B 0.1	STD	07/26/11	STD	STD	0.01	Greater than 2X bckgnd	
STD A 0.5	STD	07/26/11	STD	STD	0.01	Greater than 2X bckgnd	

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