DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406

RE: License No. 19-07538-01; Docket No. 03004544; Control No. 143643

Dear Mr. Lawyer,

In response to your May 21, 2009 request, please find the four attachments omitted from my May 13, 2009 submission to amend to license number; 19-07538-01, control number: 143643.

Kindly let me know if you need any additional information.

Sincerely,

Petro Shandruk

Petro Shandruk, RSO
Chief, Radiation Programs Branch
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Enclosed:
2 copies of Attachments 1 - 4

cc: Lillian J. Gill
Senior Associate Director, CDRH, FDA

143643

NMSS/RGN1 MATERIALS-002

ATTACHMENT 1

Removable Surface Activity Measurements

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2		
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA
BZ11108 - 1	200-1	3	8	27
BZ11108 - 2	200-2	1	7	25
BZ11108 - 3	200-3	0	7	26
BZ11108 - 4	200-4	6	7	24
BZ11108 - 5	200-5	1	7	25
BZ11108 - 6	200-6	4	8	27
BZ11108 - 7	200-7	6	8	25
BZ11108 - 8	200-8	7	8	26
BZ11108 - 9	200-9	0	7	24
BZ11108 - 10	200-10	0	7	25
BZ11108 - 11	201-1	3	7	25
BZ11108 - 12	201-2	15	9	25
BZ11108 - 13	201-3	0	7	25
BZ11108 - 14	201-4	8	8	25
BZ11108 - 15	201-5	8	8	25
BZ11108 - 16	201-6	2	7	25
BZ11108 - 17	201-7	0	7	25
BZ11108 - 18	201-8	0	7	24
BZ11108 - 19	201-9	6	8	25
BZ11108 - 20	201-10	0	7	25
BZ11108 - 21	204-1	22	10	27
BZ11108 - 22	204-2	0	7	26
BZ11108 - 23	204-3	6	8	26
BZ11108 - 24	204-4	0	7	26
BZ11108 - 25	204-5	2	8	27
BZ11108 - 26	204-6	14	8	24
BZ11108 - 27	204-7	4	7	24
BZ11108 - 28	204-8	7	8	26
BZ11108 - 29	204-9	11	9	26
BZ11108 - 30	204-10	0	7	24
BZ11108 - 31	205-1	7	8	26
BZ11108 - 32	205-2	12	9	26
BZ11108 - 33	205-3	3	8	26
BZ11108 - 34	205-4	0	7	24
BZ11108 - 35	205-5	2	8	26

Removable Surface Activity Measurements

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2		
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA
BZ11108 - 36	205-6	6	8	26
BZ11108 - 37	205-7	0	7	26
BZ11108 - 38	205-8	0	7	26
BZ11108 - 39	205-9	1	7	25
BZ11108 - 40	205-10	0	7	24
BZ11108 - 41	206-1	0	7	26
BZ11108 - 42	206-2	9	8	26
BZ11108 - 43	206-3	0	7	25
BZ11108 - 44	206-4	18	9	26
BZ11108 - 45	206-5	1	7	26
BZ11108 - 46	206-6	0	8	27
BZ11108 - 47	206-7	5	8	26
BZ11108 - 48	206-8	0	7	25
BZ11108 - 49	206-9	1	7	25
BZ11108 - 50	206-10	4	8	25
BZ11108 - 51	208-1	6	8	25
BZ11108 - 52	208-2	1	7	25
BZ11108 - 53	208-3	12	8	24
BZ11108 - 54	208-4	4	8	26
BZ11108 - 55	208-5	5	8	26
BZ11108 - 56	208-6	6	8	27
BZ11108 - 57	208-7	1	7	25
BZ11108 - 58	208-8	4	8	26
BZ11108 - 59	208-9	0	7	25
BZ11108 - 60	208-10	9	8	26
BZ11108 - 61	209-1	6	8	26
BZ11108 - 62	209-2	6	8	25
BZ11108 - 63	209-3	4	8	26
BZ11108 - 64	209-4	4	7	24
BZ11108 - 65	209-5	0	7	27
BZ11108 - 66	209-6	0	7	26
BZ11108 - 67	209-7	7	8	25
BZ11108 - 68	209-8	13	9	26
BZ11108 - 69	209-9	1	7	25
BZ11108 - 70	209-10	0	7	26

Removable Surface Activity Measurements

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2		
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA
BZ11108 - 71	210-1	2	7	26
BZ11108 - 72	210-2	6	8	26
BZ11108 - 73	210-3	0	7	25
BZ11108 - 74	210-4	0	7	26
BZ11108 - 75	210-5	0	7	24
BZ11108 - 76	210-6	1	7	25
BZ11108 - 77	210-7	1	7	26
BZ11108 - 78	210-8	1	7	25
BZ11108 - 79	210-9	0	7	26
BZ11108 - 80	210-10	0	7	26
BZ11108 - 81	212-1	0	7	26
BZ11108 - 82	212-2	1	7	26
BZ11108 - 83	212-3	0	7	26
BZ11108 - 84	212-4	8	8	24
BZ11108 - 85	212-5	7	8	25
BZ11108 - 86	212-6	6	8	25
BZ11108 - 87	212-7	1	7	26
BZ11108 - 88	212-8	0	7	25
BZ11108 - 89	212-9	4	7	25
BZ11108 - 90	212-10	6	8	25
BZ11108 - 91	Misc. Item- 1	6	8	25
BZ11108 - 92	Misc. Item- 2	1	7	26
BZ11108 - 93	Misc. Item- 3	78	14	25
BZ11108 - 94	Misc. Item- 4	9	8	26
BZ11108 - 95	Misc. Item- 5	7	8	26
BZ11108 - 96	Misc. Item- 6	27	10	25
BZ11108 - 97	Misc. Item- 7	32	10	25
BZ11108 - 98	Sealed source leak test - 1	0	7	25
BZ11108 - 99	Sealed source leak test - 2	5	8	25
BZ11108 - 100	Sealed source leak test - 3	1	7	25
BZ11108 - 101	Sealed source leak test - 4	0	7	25
BZ11108 - 106	Sealed source leak test - 9	6	8	25
BZ11108 - 107	Sealed source leak test - 10	79	14	25
BZ11108 - 108	Safe - 1	9	8	25
BZ11108 - 109	Safe - 2	3	8	25

Removable Surface Activity Measurements

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2		
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA
BZ11108 - 110	Safe - 3	46	12	26
BZ11108 - 111	Safe - 4	8	8	26
BZ11108 - 112	Safe - 5	72	15	27
BZ11108 - 113	Safe - 6	14	10	29
BZ11108 - 114	Safe - 7	17	11	29
BZ11108 - 115	Safe - 8	26	12	30
BZ11108 - 116	Safe - 9	20	9	25
BZ11108 - 117	Safe - 10	0	8	28
BZ11108 - 118	Safe - 11	9	9	28
BZ11108 - 119	Safe - 12	1	8	28
BZ11108 - 120	Safe - 13	8	8	25
BZ11108 - 121	Safe - 14	0	7	25
BZ11108 - 122	Safe - 15	2	7	25
BZ11108 - 123	Safe - 16	0	7	26
BZ11108 - 124	Safe - 17	3	8	27
BZ11108 - 125	Safe - 18	11	9	27
BZ11108 - 126	Safe - 19	0	7	25
BZ11108 - 127	Safe - 20	5	8	26
BZ11108 - 128	Shielded "yellow" box - 1, lid	10	9	26
BZ11108 - 129	Shielded "yellow" box - 1, interior	13	9	26
BZ11108 - 130	Shielded "yellow" box - 1, exterior	0	7	26
BZ11108 - 131	Large lead pig - 1	8	9	27
BZ11108 - 132	Large lead pig - 2	8	8	26
BZ11108 - 133	Lead item - 1	0	7	26
BZ11108 - 134	Lead item - 2	0	7	26
BZ11108 - 135	Lead item - 3	6	8	25
BZ11108 - 136	Lead item - 4	5	8	26
BZ11108 - 137	Lead item - 5	2	7	25
BZ11108 - 138	Lead item - 6	0	7	25
BZ11108 - 139	Lead item - 7	95	17	28
BZ11108 - 140	Lead item - 8	7	8	26
BZ11108 - 141	Lead item - 9	4	8	26
BZ11108 - 142	Lead item - 10	30	10	26
BZ11108 - 143	Lead item - 11	57	12	25
BZ11108 - 144	Lead item - 12	7	8	24

Removable Surface Activity Measurements

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2		
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA
BZ11108 - 145	Lead item - 13	28	10	26
BZ11108 - 146	Lead item - 14	5	8	26
BZ11108 - 147	Lead item - 15	19	9	25
BZ11108 - 148	Lead item - 16	32	11	27
BZ11108 - 149	Lead item - 17	3	8	26
BZ11108 - 150	Lead item - 18	0	7	26
BZ11108 - 151	Lead item - 19	24	10	25
BZ11108 - 152	Lead item - 20	19	9	26
BZ11108 - 153	Lead item - 21	3	8	26
BZ11108 - 154	Lead item - 22	23	10	26
BZ11108 - 155	Lead item - 23	13	9	27
BZ11108 - 156	Lead item - 24	11	8	25
BZ11108 - 157	Lead item - 25	0	7	26
BZ11108 - 158	Lead item - 26	7	8	26
BZ11108 - 159	Lead item - 27	14	9	25
BZ11108 - 160	Lead item - 28	28	11	27
BZ11108 - 161	Lead item - 29	7	8	26
BZ11108 - 162	Lead item - 30	0	8	27
BZ11108 - 163	Lead item - 31	2	7	25
BZ11108 - 164	Lead item - 32	5	7	25
BZ11108 - 165	Lead item - 33	24	10	25

ATTACHMENT 2

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2			
		Gross Gamma	Uncertainty (95%CL)	MDA	Radionuclide
BZ11108 - 102	Sealed source leak test - 5	8552	84	101	137Cs
BZ11108 - 103	Sealed source leak test - 6	29310	144	101	137Cs
BZ11108 - 104	Sealed source leak test - 7	5793	73	101	137Cs
BZ11108 - 105	Sealed source leak test - 8	9655	89	101	137Cs

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2			
		Gross Gamma	Uncertainty (95%CL)	MDA	Radionuclide
R1	Lead pig- top, interior, labeled "ICN P"	297271	152	50	137Cs
R3	Lead pig- top, interior, not labeled	31389	51	50	137Cs
R5	Lead base, not labeled	5240	23	48	137Cs
R5	Lead base, not labeled	15020	31	58	133Ba

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2			
		Gross Alpha	Uncertainty (95%CL)	MDA	Radionuclide
R1	Lead pig- top, interior, labeled "ICN P"	89250	60	7	241Am
R5	Lead base, not labeled	16800	26	7	241Am

Swipe Sample ID Number	Swipe Sample Location	Removable Surface Activity in DPM/100cm2			
		Gross Alpha/Beta	Uncertainty (95%CL)	MDA	Radionuclide
R2	Lead pig- top, interior, labeled "57Co"	391867	42	14	238U, 234Th

ATTACHMENT 3

Direct Measurements - Safe Interior

Sample Point	Bkg (counts)	Gross (counts)	Count time (in min)	Total Surface Activity[1] in DPM/100cm2		
				Gross Alpha	Uncertainty[2]	MDA
Interior door - lower left	6	399	1	6550	657	193
Interior door - lower left mid	6	404	1	6633	661	193
Interior door - lower right mid	6	325	1	5317	594	193
Interior door - lower right mid	6	286	1	4667	558	193
Interior door - middle left	6	450	1	7400	698	193
Interior door - middle left mid	6	707	1	11683	872	193
Interior door - middle right mid	6	375	1	6150	638	193
Interior door - middle right mid	6	359	1	5883	624	193
Interior door - top left	6	453	1	7450	700	193
Interior door - top left mid	6	520	1	8567	749	193
Interior door - top right mid	6	476	1	7833	717	193
Interior door - top right	6	366	1	6000	630	193
Floor - left front	12	93	1	1350	335	271
Floor - left mid front	12	100	1	1467	346	271
Floor - right mid front	12	88	1	1267	327	271
Floor - right front	12	99	1	1450	344	271
Floor - left rear	12	118	1	1767	372	271
Floor - left mid rear	12	110	1	1633	361	271
Floor - right mid rear	12	94	1	1367	336	271
Floor - right rear	12	135	1	2050	396	271

[1] - $E_{weighted, total}$; 0.06, probe active area 126cm2

[2] - at the 95% confidence level

Averaged Activity

4824 (DPM/100cm2)

Direct Measurements - Safe Interior

Sample Point	Bkg (counts)	Gross (counts)	Count time (in min)	Total Surface Activity[1] in DPM/100cm2		
				Gross Beta	Uncertainty[2]	MDA
Interior door - lower left	201	1269	1	16952	1193	1049
Interior door - lower left mid	201	1408	1	19159	1248	1049
Interior door - lower right mid	201	1222	1	16206	1174	1049
Interior door - lower right mid	201	1006	1	12778	1081	1049
Interior door - middle left	201	1779	1	25048	1384	1049
Interior door - middle left mid	201	2557	1	37397	1634	1049
Interior door - middle right mid	201	1325	1	17841	1215	1049
Interior door - middle right mid	201	1204	1	15921	1166	1049
Interior door - top left	201	1452	1	19857	1265	1049
Interior door - top left mid	201	1662	1	23190	1343	1049
Interior door - top right mid	201	1749	1	24571	1374	1049
Interior door - top right	201	1226	1	16270	1175	1049
Floor - left front	258	336	1	1238	758	1188
Floor - left mid front	258	298	1	635	734	1188
Floor - right mid front	258	316	1	921	745	1188
Floor - right front	258	337	1	1254	759	1188
Floor - left rear	258	319	1	968	747	1188
Floor - left mid rear	258	436	1	2825	820	1188
Floor - right mid rear	258	316	1	921	745	1188
Floor - right rear	258	460	1	3206	834	1188

[1] - $E_{weighted, total}$; 0.063, probe active area 126cm2

[2] - at the 95% confidence level

Averaged Activity

12858 (DPM/100cm2)

ATTACHMENT 4

The lower wall area was defined as the surface area from the floor to a height of eight feet. Surface scans were designated to cover 100% of accessible floor and 50% of accessible lower wall areas. Surface scans were designated to cover 10% of upper wall and ceiling areas. Scoping surveys were designed to evaluate levels of 1) total surface activity using surface scans as well as static measurements, and 2) removable surface contamination using smear samples. Smear sample locations were determined using the surveyor's professional judgment. These surveys would focus on surfaces deemed "high risk areas" e.g. floors, sinks and lower walls. Any area found to have residual surface contamination was designated for further evaluation as outlined below;

Surface Scans –any surface area found to be greater than twice the reference background for the surface matrices in beta mode, or 2 cpm above the reference background for the matrices being evaluated in the alpha mode.

Smears – any activity detected above the minimum detectable level.

Any area found to be at the investigative level for surface scans would be designated for evaluation in both alpha and beta mode. Further evaluations would be made using static measurements and smears to quantify the level of the contamination and better define the area. Any area where residual activity is identified at the investigative level would be sufficient cause to designate the area as a usage area, thereby increasing the coverage area for surface scans.

Table 1

Radionuclide	Symbol	Acceptable Screening Levels ($dpm/100cm^2$)
137-Cesium	^{137}Cs	2.4E+04
133-Barium	^{133}Ba	5.5E+04
241-Americium	^{241}Am	26
238Uranium+C	^{238}U	250

Survey instruments were selected based on the detection sensitivities to the radiations of concern. The detection sensitivity of large area gas proportional detectors was evaluated to ensure detection levels are within acceptable parameters (10%-50% of the DCGL). These detectors were equipped with 0.8mm thick windows. This meant the detector could be operated in an alpha or beta mode. The DCGL's for ^{238}U and ^{241}Am are low compared to the other contaminants. In order to meet the acceptable detection parameter of 10% to 50% of the DCGL, alpha must be evaluated independently. The strategy for evaluating residual surface contamination with ^{133}Ba as a possible contaminant was to scale the ^{133}Ba to the total activity and calculate a gross activity DCGL determined

using the ratio of contaminants identified in Table 2 and applying it using formula 4-4 as found in NUREG-1575 (December 1997).

Table 2

Radionuclide	Ratio
137-Cesium	96%
133-Barium	4%

The $DCGL_{weighted}$ ($DCGL_w$) was found to be 24,554 dpm/100cm^2. One half the $DCGL_w$ would be 12,277 dpm/100cm^2. One half the $DCGL_w$ was next determined to be 6,859 cpm/100cm^2 by converting from a unit of radioactivity to counts per minute using a value of 0.096 for $E_{weighted,\ total}$. The total efficiency (E) was weighted according to the relative ratios. The surface efficiency (E_s) of 0.5 is applied for greater than 0.4 MeV beta emitting radionuclides.

$$E_{weighted,\ total} = (0.2 \times 0.5 \times 96\%) + (0 \times 4\%)$$

The active probe surface area of 582 cm^2 was also used in converting the $DCGL_w$ from a unit of radioactivity to cpm.

The gross alpha $DCGL_{weighted}$ ($DCGL_w$) was found to be 89 dpm/100cm^2. One half the $DCGL_w$ would be 44 dpm/100cm^2. One half the gross alpha $DCGL_w$ was next determined to be 12 cpm/100cm^2 by converting from a unit of radioactivity to counts per minute using a value of 0.2619 for $E_{weighted,\ total}$. The total efficiency (E) was weighted according to the relative ratios. The surface efficiency (E_s) of 0.25 is applied for alpha emitting radionuclides.

$$E_{weighted,\ total} = (0.18 \times 0.25 \times 79\%) + (0.18 \times 0.25 \times 21\%)$$

The active probe surface area of 582 cm^2 was also used in converting the $DCGL_w$ from a unit of radioactivity to cpm.

2.1 Field Measurements, Methods and Instrumentation

Surface scans and static measurements for beta emitting radionuclides were made using scaler/rate meters equipped with large area gas proportional detectors (Ludlum model 43-37 and 43-68). Variations in background readings of up to 400cpm in beta mode were found throughout the building. The contributing factors were determined to be 1) variations in the composition of surface matrices as well as 2) the presence of radon.

The Scan MDC for a 43-37 detector on a concrete floor surface was determined to be 614 dpm/100cm^2 using an averaged background of 934 cpm. The Scan MDC is well below the $DCGL_w$ of 24,554 dpm/100cm^2. The following variables were used in determination of the Scan MDC for