DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration
Center for Devices and Radiological Health

Office of Communication, Education, and Radiation Programs
Division of Mammography Quality and Radiation Programs
10903 New Hampshire Ave. Bldg 66, Rm 4521
Silver Spring, MD 20993
(301) 796-5710 phone (301) 847-8502 fax

FACSIMILE TRANSMISSION

Date: November 24, 2010

J-6

From: **Petro Shandruk**

Send to: **Dennis R. Lawyer**
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission

Telephone #
301/796-5889

RE: **Follow-up to October 6, 2010 NRC Letter**
Docket No. 03004544
Control No. 573589

19-07532-01

-This confirms that all sealed sources at the facility were leak tested. No such sources had been removed since arriving at the White Oak location.
-The attachments should address Item 4 in the letter which dealt with leak test results.

Petro Shandruk

FAX Number: 610/337-5269

Number of Pages to follow: 11

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573589

Dade Moeller & Associates®

Analytical & Calibration Services
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Gaithersburg, Maryland 20877
800.871.7930
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www.RadiationSafetyAcademy.com

June 22, 2010

Mary Walker
Food and Drug Administration
Ionizing Radiation Measurements Laboratory
10903 New Hampshire Avenue
W062-4126
Silver Spring, Maryland 20993-0002

Re: Sample Analysis Report of Seven (7) Unknowns

Dear Ms. Walker:

As described in the proposal dated June 4, 2010, Dade Moeller & Associates, Inc (Dade Moeller) was retained to perform a survey of seven (7) "unknown" radioactive items for the Food and Drug Administration (FDA) at their Silver Spring, Maryland location. On June 14, 2010, Dade Moeller health physicist, Mr. Mike Jedlicka carefully scanned each "unknown" item with the hand-held radiation detection equipment located in **Table 1**. Furthermore, swab type samples were collected on each "unknown" item (multiple locations per item) to access for removable radioactive contamination. The results of the scans and sample analysis of the "unknowns" are located in **Table 2** and summarized immediately following the table. Following the completion of the scans and swab sample collection, additional samples were collected of the areas that these "unknowns" were stored as well as the area used by Dade Moeller to scan and sample the "unknowns". **Table 3** contains the results of the additional samples collected by Dade Moeller to ensure no contamination was spread during the work performed; as well as the results for the samples collected on the floor type lead storage safe.

Table 1 – Radiation Detection Equipment

Radiation Detection Equipment			
Meter Number	**Description**	**Serial Number**	**Calibration Date**
1	Ludlum Model 3 equipped with a Ludlum Model 44-9 PancakeGM (PanGM), Ludlum Model 43-2 Alpha Scintillator (ZnS), and Ludlum Model 44-3 Low Energy Gamma Scintillator (NaI).	Model 3 – 164026 Model 44-9 – PR168846 Model 43-2 – PR171007 Model 44-3 – PR168781	April 20, 2010
2	Bicron Fieldspec Handheld MCA	00F3-287	Self Calibrating

Table 2 – Results of Scans and Samples Analysis of Unknowns

Results Table – Unknowns										
		Maximum Count Rate or Dose Rate								
Unknown Number	**Description**	**PanGM Results (kcpm)**	**ZnS Results (kcpm)**	**NaI Results (kcpm)**	**Dose Rate (μR/hr)**	**Sample Number**	**Location**	**Gamma Analysis Results**	**Alpha / Beta Analysis Results (dpm)**	**Nuclide Identified**
1	Lead "pig" bottom portion, approx 1" in diameter x 1" high. See Picture 1	60	n/a	n/a	4-6	1A	Plastic Bag	n/a	n/a	Pb-210
						1B	Inside – Side	323.7 cpm	19,117.0 dpm	
						1C	Inside – Bottom	238.9 cpm	14,181.5 dpm	

		Maximum Count Rate or Dose Rate								
Unknown Number	Description	PanGM Results (kcpm)	ZnS Results (kcpm)	NaI Results (kcpm)	Dose Rate (µR/hr)	Sample Number	Location	Gamma Analysis Results	Alpha / Beta Analysis Results (dpm)	Nuclide Identified
2	Lead storage container with lid, approx 5" diameter x 2" tall (excluding handle). See Picture 2	10	3	n/a	22.5	2A	Plastic Bag	n/a	n/a	Unknown, to low of activity to positively ID – further analysis required.
						2B	Inside – Bottom	n/a	130 cpm	
						2C	Inside – Bottom	n/a	199 cpm	
						2D	Outside – Top	n/a	n/a	
3	Lead "pig" top, approx 1.5" in diameter. See Picture 3	n/a	n/a	n/a	30	3A	Plastic Bag	n/a	n/a	Cs-137
						3B	Inside – Top	489.9 dpm	404 dpm	
						3C	Outside – Top	n/a	n/a	
4	Disc labeled (MOD 40108-3 S/N I01 C-14; 1mC; 1-77; approx 1" in diameter x 0.25" tall.	0.4	n/a	n/a	n/a	4A	Plastic Bag	n/a	n/a	C-14 (by label only)
						4B	Top	n/a	n/a	
						4C	Bottom	n/a	n/a	
5	Small plastic disc with orange foil at center; approx 0.75" in diameter and 0.25" tall. See Picture 5	1	n/a	1.6	n/a	5A	Plastic Bag	n/a	n/a	Unknown, to low of activity to positively ID – further analysis required.
						5B	Top	n/a	n/a	
						5C	Bottom	n/a	n/a	
6	Bottom of lead "pig" Bottom of unknown #3. Approx 1.5" in diameter and 1" high. See Picture 6	8	n/a	2.5	n/a	6A	Plastic Bag	n/a	n/a	Cs-137
						6B	Inside – Bottom	1,920.9 dpm	1,986 dpm	
7	Thoriated Optical Lens; approx 5.5" in diameter and 3" tall. See Picture 7	n/a	n/a	n/a	3550 (3.55 mR/hr)	7A	Plastic Bag	n/a	n/a	Th-232
						7B	All Surfaces	n/a	n/a	

Based on the results located in **Table 2** above, we have summarized the items as follows:

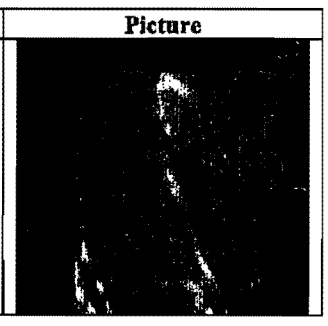
- **Item 1** – Bottom portion to a lead storage "pig." The samples taken inside the lead "pig" exhibited an average of approximately 16,650 dpm of Lead-210 (Pb-210). Samples 1B and 1C showed positive results for Pb-210 in both the liquid scintillation counter (LSC) as well as gamma counter.
- **Item 2** – Lead storage container. Sample analysis yielded an average of approximately 165 cpm on the LSC for the samples collected on the inside bottom (samples 2B and 2C) of the storage container; no elevated gamma counts were seen with either sample. No dpm value was accessed to these samples due to the inability to positively identify the nuclide. Further testing is required for a positive ID.
- **Item 3** – Top to lead storage "pig." The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was seen by the LSC and gamma counter for Cs-137. An average of approximately 447 dpm of removable Cs-137 was seen by the LSC and gamma counter.
- **Item 4** – This item was labeled as being Carbon-14 (C-14). Approximately 400 cpm was seen with the hand-held Model 44-9 PanGM. No removable activity was detected during sample analysis. Source ID of C-14 based on label and low count rate of beta emission only.

- **Item 5** – Item exhibited 1,000 and 1,600 cpm with the Model 44-9 PanGM and Model 44-3 NaI, respectively. No removable activity was detected during sample analysis. A positive ID could not be made due to low activity without further analytical testing.
- **Item 6** – Bottom to lead storage "pig." This is the bottom portion to Item #3. The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was seen by the LSC and gamma counter for Cs-137. An average of approximately 1,953 dpm of removable Cs-137 was seen by the LSC and gamma counter.
- **Item 7** – This item is a Thoriated lens (Thorium-232 or Th-232) used in optical systems and older camera lens. No removable activity was detected during sample analysis.

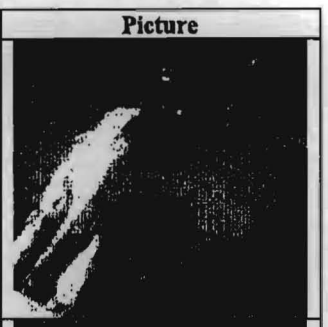
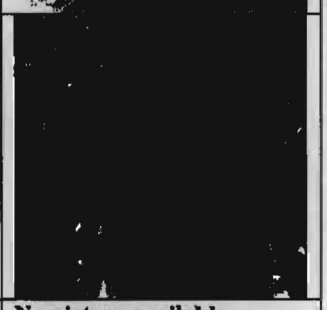
Table 3 – Results of Additional Samples Collected and Samples of Floor Type Lead Storage Safe

Results Table – Work/Storage Areas and Lead Storage Safe			
Sample Number	**Description or Location**	**Gamma Analysis Results**	**Alpha / Beta Analysis Results**
1	Work Area	~ Background	~ Background
2	Work Area	~ Background	~ Background
3	Drawer – Storage Location	~ Background	~ Background
4	Cabinet – Top Shelf (Storage Location)	~ Background	~ Background
5	Cabinet – Bottom Shelf (Storage Location)	~ Background	~ Background
6	Outside Drawer	~ Background	~ Background
7	Outside Cabinet	~ Background	~ Background
8	Bench Area Above Storage Drawer	~ Background	~ Background
9	Floor (Storage Location)	~ Background	~ Background
10	Floor (Work Area)	~ Background	~ Background
11	Lead Storage Safe – Outside Top	~ Background	~ Background
12	Lead Storage Safe – Outside Bottom	~ Background	~ Background
13	Lead Storage Safe – Inside Top	~ Background	~ Background
14	Lead Storage Safe – Inside Bottom Sides	~ Background	~ Background
15	Lead Storage Safe – Inside Bottom	~ Background	~ Background

Item Pictures

Item Number	Picture
1	

June 22, 2010

Item Number	Picture
2	
3	
4	No picture available
5	
6	
7	

All samples were analyzed at Dade Moeller's Radio-Analytical & Calibration Laboratory (RACL) in Gaithersburg, Maryland. The RACL follows a rigorous Quality Assurance program that meets and follows the standards provided under ISO/IEC 17025:2005, NELAC Standard, ANSI NQA-1, ANSI N323A, MDE License MD-31-244-01 and other applicable standards. All RACL personnel are trained in key aspects of the quality system. The original analytical data are maintained by the RACL for regulatory purposes. Copies of raw data, analytical standard operating procedures, and QA/QC information are available upon request.

Please let me know if you have questions or concerns about the above materials. Dade Moeller is available to assist the FDA in the disposal of these materials at your request.

Sincerely,

Mike Jedlicka
Health Physicist and Laboratory Manager
Dade Moeller & Associates, Inc.
Radio-Analytical & Calibration Laboratory

Dade Moeller & Associates®

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July 19, 2010

Mary Walker
Food and Drug Administration
Ionizing Radiation Measurements Laboratory
10903 New Hampshire Avenue
W062-4126
Silver Spring, Maryland 20993-0002

Re: Sample Analysis Report of Seven (7) Unknowns

Dear Ms. Walker:

As described in the proposal dated June 4, 2010, Dade Moeller & Associates, Inc (Dade Moeller) was retained to perform a survey of seven (7) "unknown" radioactive items for the Food and Drug Administration (FDA) at their Silver Spring, Maryland location. On June 14, 2010, Dade Moeller health physicist (HP), Mr. Mike Jedlicka carefully scanned each "unknown" item with the hand-held radiation detection equipment located in **Table 1**. Furthermore, swab type samples were collected on each "unknown" item (multiple locations per item) to assess for removable radioactive contamination. The results of the scans and sample analysis of the "unknowns" are located in **Table 2**. Following the completion of the scans and swab sample collection, additional samples were collected of the areas that these "unknowns" were stored as well as the area used by Dade Moeller to scan and sample the "unknowns." **Table 3** contains the results of the additional samples collected by Dade Moeller to ensure no contamination was spread during the work performed, as well as the results for the samples collected on the floor type lead storage safe at the FDA's request. As of June 22, 2010, only five (5) of the seven (7) "unknowns" were identified as listed in **Table 2**.

Further analysis was completed on July 14, 2010 of the two (2) remaining "unknowns." Unknown #2 and Unknown #5 were picked up by Dade Moeller and hand delivered to Dade Moeller's Radio-Analytical & Calibration Laboratory on July 12, 2010. Unknown #2 (lead pig) was soaked with deionized water for 30 minutes and scraped with a razor blade to remove the surface contamination. The water was pipetted into two (2) twenty milliliter (20 mL) glass vials for analysis. Unknown #5 was subject to direct gamma analysis. The results of the analyses are listed in **Table 4**. All "unknowns" are summarized using the data located in **Table 2** and **Table 4** of this report.

Table 1 – Radiation Detection Equipment

Radiation Detection Equipment			
Meter Number	**Description**	**Serial Number**	**Calibration Date**
1	Ludlum Model 3 equipped with a Ludlum Model 44-9 PancakeGM (PanGM), Ludlum Model 43-2 Alpha Scintillator (ZnS), and Ludlum Model 44-3 Low Energy Gamma Scintillator (NaI).	Model 3 – 164026 Model 44-9 – PR168846 Model 43-2 – PR171007 Model 44-3 – PR168781	April 20, 2010
2	Bicron Fieldspec Handheld MCA	00F3-287	Self Calibrating

Table 2 – Results of Scans and Sample Analysis of Unknowns (as of June 22, 2010)

Results Table – Unknowns										
		Maximum Count Rate or Dose Rate								
Unknown Number	Description	PanGM Results (kcpm)	ZnS Results (kcpm)	NaI Results (kcpm)	Dose Rate (µR/hr)	Sample Number	Location	Gamma Analysis Results	Alpha / Beta Analysis Results (dpm)	Nuclide Identified
1	Lead "pig" bottom portion, approx 1" in diameter x 1" high. See Picture 1	60	n/a	n/a	4-6	1A	Plastic Bag	n/a	n/a	Pb-210
						1B	Inside – Side	323.7 cpm	19,117.0 dpm	
						1C	Inside – Bottom	238.9 cpm	14,181.5 dpm	
2	Lead storage container with lid, approx 5" diameter x 2" tall (excluding handle). See Picture 2	10	3	n/a	22.5	2A	Plastic Bag	n/a	n/a	Unknown, too low of activity to positively ID – further analysis required.
						2B	Inside – Bottom	n/a	130 cpm	
						2C	Inside – Bottom	n/a	199 cpm	
						2D	Outside – Top	n/a	n/a	
3	Lead "pig" top, approx 1.5" in diameter. See Picture 3	n/a	n/a	n/a	30	3A	Plastic Bag	n/a	n/a	Cs-137
						3B	Inside – Top	489.9 dpm	404 dpm	
						3C	Outside – Top	n/a	n/a	
4	Disc labeled (MOD 40108-3 S/N 101 C-14; 1mC; 1-77; approx 1" in diameter x 0.25" tall.	0.4	n/a	n/a	n/a	4A	Plastic Bag	n/a	n/a	C-14 (by label only)
						4B	Top	n/a	n/a	
						4C	Bottom	n/a	n/a	
5	Small plastic disc with orange foil at center; approx 0.75" in diameter and 0.25" tall. See Picture 5	1	n/a	1.6	n/a	5A	Plastic Bag	n/a	n/a	Unknown, too low of activity to positively ID – further analysis required.
						5B	Top	n/a	n/a	
						5C	Bottom	n/a	n/a	
6	Bottom of lead "pig" Bottom of unknown #3. Approx 1.5" in diameter and 1" high. See Picture 6	8	n/a	2.5	n/a	6A	Plastic Bag	n/a	n/a	Cs-137
						6B	Inside – Bottom	1,920.9 dpm	1,986 dpm	
7	Thoriated Optical Lens; approx 5.5" in diameter and 3" tall. See Picture 7	n/a	n/a	n/a	3550 (3.55 mR/hr)	7A	Plastic Bag	n/a	n/a	Th-232
						7B	All Surfaces	n/a	n/a	

Table 3 – Results of Additional Samples Collected and Samples of Floor Type Lead Storage Safe

Results Table – Work/Storage Areas and Lead Storage Safe			
Sample Number	Description or Location	Gamma Analysis Results	Alpha / Beta Analysis Results
1	Work Area	~ Background	~ Background
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10	Floor (Work Area)	~ Background	~ Background
11	Lead Storage Safe – Outside Top	~ Background	~ Background
12	Lead Storage Safe – Outside Bottom	~ Background	~ Background
13	Lead Storage Safe – Inside Top	~ Background	~ Background
14	Lead Storage Safe – Inside Bottom Sides	~ Background	~ Background
15	Lead Storage Safe – Inside Bottom	~ Background	~ Background

Table 4 – Results of Sample Analysis of Unknown #2 and #5 (July 14, 2010)

Results of Unknown # 2 and #5					
Unknown Number	Description	Sample Number	Location	Gamma Analysis Results	Nuclide Identified
2	Lead storage container with lid, approx 5" diameter x 2" tall (excluding handle). See Picture 2	1A	dH_2O and scrapings from inside bottom of lead pig	2669.20 cpm	Ra-226
		1B	dH_2O and scrapings from inside bottom of lead pig	3861.68 cpm	Ra-226
5	Small plastic disc with orange foil at center; approx 0.75" in diameter and 0.25" tall. See Picture 5	1	Direct gamma analysis	7804.82 cpm	Co-57

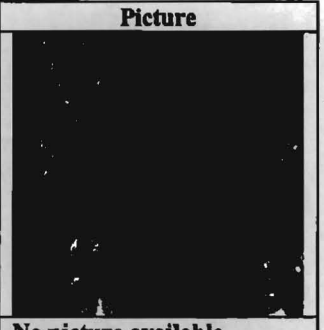
Based on the results located in **Tables 2** and **4** above, we have summarized the items as follows:

- **Item 1** – Bottom portion to a lead storage "pig." The samples taken inside the lead "pig" exhibited an average of approximately 16,650 dpm (7.5 nCi) of Lead-210 (Pb-210). Samples 1B and 1C showed positive results for Pb-210 in both the liquid scintillation counter (LSC) as well as gamma counter.

- **Item 2** – Lead storage container. Sample analysis yielded an average of approximately 165 cpm on the LSC for the samples collected on the inside bottom (samples 2B and 2C) of the storage container; no elevated gamma counts were seen with either sample. Samples was subjected to soak with deionized water for 30 minutes and scraped with a razor blade to remove the surface contamination. The water was pipetted into two (2) twenty milliliter (20 mL) glass vials for analysis. Gamma analysis yielded a total of approximately 6,531 counts per minute (summation of Sample 1A and 1B, Table 4) of Radium-226 (Ra-226) that was removed from the lead pig. Utilizing a Ra-226 standard, approximately 6,941 dpm (3.13 nCi) of Ra-226 was removed from the lead pig.
- **Item 3** – Top to lead storage "pig." The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was seen by the LSC and gamma counter for Cs-137. An average of approximately 447 dpm (0.2 nCi) of removable Cs-137 was made by the LSC and gamma counter.
- **Item 4** – This item was labeled as being Carbon-14 (C-14). Approximately 400 cpm was measured with the hand-held Model 44-9 PanGM. No removable activity was detected during sample analysis. The source ID of C-14 based on label and low count rate of beta emission only.
- **Item 5** – Item exhibited 1,000 and 1,600 cpm with the Model 44-9 PanGM and Model 44-3 NaI, respectively. No removable activity was detected during sample analysis. Direct gamma analysis was performed on this source. Results yielded an approximate activity of 27,122 dpm (12.22 nCi) of Cobalt-57 (Co-57).
- **Item 6** – Bottom to lead storage "pig." This is the bottom portion to Item #3. The Bicron Fieldspec identified the contamination to be Cesium-137 (Cs-137). Additionally, a positive ID was made by the LSC and gamma counter for Cs-137. An average of approximately 1,953 dpm (0.88 nCi) of removable Cs-137 was found by the LSC and gamma counter.
- **Item 7** – This item is a Thoriated lens (Thorium-232 or Th-232) used in optical systems and older camera lens. No removable activity was detected during sample analysis.

Item Pictures

Item Number	Picture
1	
2	

Item Number	Picture
3	
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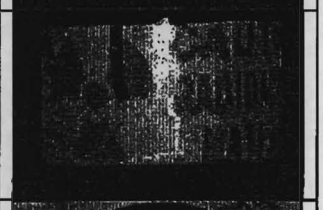
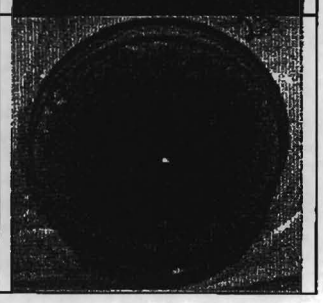
6	
7	

All samples were analyzed at Dade Moeller's Radio-Analytical & Calibration Laboratory (RACL) in Gaithersburg, Maryland. The RACL follows a rigorous Quality Assurance program that meets and follows the standards provided under ISO/IEC 17025:2005, NELAC Standard, ANSI NQA-1, ANSI N323A, MDE License MD-31-244-01 and other applicable standards. All RACL personnel are trained in key aspects of the quality system. The original analytical data are maintained by the RACL for regulatory purposes. Copies of raw data, analytical standard operating procedures, and QA/QC information are available upon request.

Please let me know if you have questions or concerns about the above materials. Dade Moeller is available to assist the FDA in the disposal of these materials at your request.

Sincerely,

Mike Jedlicka
Health Physicist and Laboratory Manager
Dade Moeller & Associates, Inc.
Radio-Analytical & Calibration Laboratory