DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration

Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MA 01890

REC RG1 09 12'16 AM10:25

Date: September 8, 2016

Q-5

Betsy Ullrich, Senior Health Physicist
Mail Control No. 591011
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

Subject: Request for additional Information, Mail Control No. 591011

Dear Ms. Ullrich: 03004675

This is in reference to your letter of August 19, 2016 regarding our request for renewal of our NRC License No. 20-08361-01 and your telephone call to our Radiation Safety Officer on August 29, 2016

Our response to your questions is attached.
If you have any further questions, please let us know

Sincerely,

Digitally signed by Brian L. Baker -S
Date: 2016.09.08 13:50:56 -04'00'

Brian L. Baker, Center Director, WEAC

591011
NMSS/RGN1 MATERIALS-002

Response to Questions *Italicized*

1. Your current license lists a location at 19701 Fairchild, Irvine, California as using nickel-63 (Ni-63) foils only; however, this location is not listed on your renewal application. Confirm if this address should be listed on the renewed license. If not, confirm if all Ni-63 sources were transferred to an authorized location, and if any of any residual contamination remains at that location. If only sealed sources were possessed there, and none of the sources leaked, state that.

   RESPONSE: The address at 19701 Fairchild, Irvine, California should not be listed on the renewed license. The last Nickel-63 source at this location was transferred to Oregon State University, Oregon Radioactive Materials License Number ORE-90005, in 2013. Only sealed sources (Electron Capture Detectors in Gas Chromatographs) were possessed there and none of the sources leaked according to our leak test records. In the spirit of ALARA, we conducted wipe tests in the Gas Chromatograph Lab and found no results significantly above background (Attachment A).

2. Condition 10 of your current license authorizes the use of licensed material in the form of sealed sources at temporary job sites anywhere in the United States. However, this was not requested in the renewal application. Confirm if this authorization should be retained, or if you intended that it be removed from the license.

   RESPONSE: This authorization should be retained

3. The following issues refer to the byproduct materials requested in Item 5, Radioactive Materials, of your application:
   a. The broad authorization of radionuclides with atomic numbers 1 through 83, 10 millicuries each and not to exceed 1 Ci total, could include the following items: barium 133, 250 microcuries and Cs-137, 200 microcuries, both in the form of calibration sources. Confirm if you still want them listed as individual line items of the renewed license, or if the broad authorization is sufficient.

      RESPONSE: The broad authorization is sufficient

   b. The renewed license could be written with a separate authorization for radionuclides with atomic numbers 1 through 83 and half-lives less than or equal to 120 days. This line item could have an authorization with larger limits which would not affect your financial assurance or decommissioning funding plan, and would provide greater flexibility. For example, a limit of 250 millicuries per radionuclide and 2 curies total would include your requested authorizations for chromioum-51, gallium-67, selenium 75, technetium 99m, indium111, indium 114m and xenon-133 as well as allow other such short-lived radionuclides. Note that the much larger quantities requested for molybdenum-99 (25 curies), iodine-131 (1.5 curies) and samarium-153 (1 curie) would still be separate line items with this example. If you want to request a separate limit for short-lived radionuclides, propose an amount per radionuclide and a total quantity.

RESPONSE: Per your example, please add the following line items (please note that we have increased our original request to provide greater flexibility for the potential of expanded sample collection):

1. *For radionuclides with atomic numbers 1 through 83 and half-lives less than or equal to 120 days: 250 millicuries per radionuclide and 2 curies total.*
2. *Molybdenum-99 (50 curies)*
3. *Iodine-131 (3 curies)*
4. *Xenon-133 (1.5 curies)*
5. *Samarium-153 (2 curie)*

c. Same as b

d. The renewed license could be written with a separate authorization for radionuclides with atomic number 84 through 96, in order to eliminate a number of line items and provide more flexibility. For example, a limit of 1 millicurie per radionuclide and 5 millicuries total would include all the following radionuclides requested on your license: radium-226, radium-228, neptunium-237, neptunium-239, polonium, americium, actinium, and curium. If you want to request a separate limit for radionuclides with atomic numbers 84 through 96, propose an amount per radionuclide and a total quantity.

RESPONSE: Per your example, please add the following line item

1. *For radionuclides with atomic number 84 through 96; limit of 1 millicurie per radionuclide and 5 millicuries total*

e. The following radionuclides are listed as line items on the current license, in "any" form and in 300 millicuries to 3 curie quantities, but were not requested as line items in the renewal application: phosphorus-32, cobalt-60, nickel-63, strontium-89, yttrium-90, Indium-114, and cesium-137. These radionuclides continue to be authorized in your authorization(s) for any radionuclide with atomic numbers 1 through 83 up to 10 millicuries per radionuclide. In addition to any new research with these radionuclides, the broad authorization includes any residual contamination from previous activities with the larger quantities of these radionuclides. No response to this item is required.

RESPONSE: We have no knowledge of residual contamination from previous activities with larger quantities of these radionuclides

f. Your current license lists Item MM as 100 millicuries total of cadmium-109 in sealed sources, and Item PP as 5 millicuries total of americium-241 (Am-241) in sealed sources. Both of these line items are listed on the current license for use in NITON Corporation Model XL Series x-ray fluorescence analyzer devices. However, you did not request these items in your renewal application. Confirm that these sources and/or devices have been transferred or disposed of properly.

i. *RESPONSE: The Model XRF Analyzer containing both sources was transferred to Thermo Fisher Scientific, Massachusetts Radioactive Materials License Number MA 55-0238, in 2011.*

g. Your renewal application Item 6, "Purpose for which licensed material will be used", states that Items MM and NN are in storage as waste. These items are 0.02 millicuries of Am-241 in an Isotope Products laboratory Model 553-61 source, and 0.1 millicuries of radium-226 (Ra-226) in an Amersham Model 4904-E-15 source. Confirm if these sources are in use for instrument calibration as listed in Item 5, or if they are in storage as waste, pending disposal, as listed in Item 6.

RESPONSE: These sources are in storage as waste, pending disposal as listed in ITEM 6

h. Your renewal application Item B, hydrogen-3 (tritium) in any form, 10 curies, could also cover the 500 millicuries of tritium as foils in electron capture detectors. If you want a separate line item for the tritium in electron capture devices (ECDs), please provide the manufacture(s) and model number(s) for those devices.

RESPONSE: We do not want a separate line item for tritium in electron capture devices (ECDs),

i. Item M (Ra-226) of your renewal application requests 1 millicurie in any form; this authorization could include Item NN of the renewal application, for 0.1 millicurie radium-226 in an Amersham Model 4904-E-15 calibration source. Page 19 of your license application refers to radioactive antiques in storage. If any Ra-226 items are possessed pursuant to the general licenses listed in 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources," or 31.12, "General license for certain items and self-luminous products containing radium-226," they do not need to be listed on your specific license of broad scope. Confirm if you want one line item, or two line items, for radium-226 on the renewed license. If one line item for radium-226 is preferred, in any form, confirm the total quantity requested.

RESPONSE: We see no need for a separate line item for Radium-226. Radium (Atomic Number 88) should be covered by the general line item addressed in Question 3d "For radionuclides with atomic number 84 through 96; limit of 1 millicurie per radionuclide and 5 millicuries total".

j. Item JJ of your renewal application requests 150 millicuries of Ni-63 in the form of foils in electron capture devices (ECDs). Confirm if the device manufacturer and model numbers are the same as those listed in Item LL of your current license. Provide any additions or corrections to the list.

RESPONSE: All of our laboratories only report having possession of Generally Licensed Electron Capture Devices (ECD) with the exception of St Louis. We would like to keep this item in case we discover older ECDs during future decommissioning activities.

k. Confirm that you intend to increase the quantity of tritium, in any form, for use at the Jamaica, New York location, from 0.5 millicuries as listed on the current license, to 0.5 curies as requested in your renewal application.

RESPONSE: We would like to retain our current amount of 0.5 millicuries as listed on our current license

l. Your renewal application listed Item OO as a separate limit for use of tritium in any form at the Jamaica, NY location; and Item PP as a separate limit for use of Ni-63 foils in ECDs at the St. Louis, Missouri location. 1) Confirm if you want separate line items under Authorized Materials for these items, or if these should be included under the overall license limits in Items B and JJ, respectively, as listed in the renewal application. If so, the limitation for these locations could still be listed in Condition 10 of the license, without affecting the total quantities of materials authorized by the conditions 6, 7, and 8 of the license. 2) the current license authorizes the use of Ni-63 foils at the Jamaica, New York location, but this was not requested in the renewal application. Confirm if this authorization should be retained for this location. Please note that the current license limits the quantities of licensed materials under Items 6, 7 and 8; the limits written at the locations listed in Item 10 of the current license are not in addition to materials listed under items 6, 7, and 8 but rather provide restrictions in the amounts that can be used at those locations.

RESPONSE:
1) We would like separate line items in Condition 10 of the license. We want to provide restrictions in the amounts and types of radioactive materials that can be used at those locations.
2) Jamaica, New York no longer has any Electron Capture Detectors. These ECDs were returned to Agilent Technologies, NRC License Number 07-28762-01, in 2015.

4. The following issues refer to the source materials requested in Item 5, Radioactive Materials, of your application:

   a. Your current license lists the authorization for uranium-232 (U-232) as 5.0 micrograms, and you renewal application requests 100 microcuries. Our conversion of 100 microcuries of U-232 is equal to 4.5 micrograms. Confirm if you are requesting this small decrease in U-232, or if you are using a specific activity that is different than 22.3 curies per gram (Ci/g).

RESPONSE: We confirm that we are requesting a small decrease in U-232

b. Your current license lists the authorization for uranium-236 (U-236) as 400 milligrams, and you renewal application requests 30 microcuries. Our conversion of 30 microcuries of U-236 is equal to 459 milligrams. Confirm if you are requesting this small increase in U-236, or if you are using a specific activity that is different than 6.54E-5 Ci/g.

RESPONSE: We confirm that we are requesting a small increase in U-236

c. Your current license lists the authorization for uranium-237 (U-237) as 0.03 nanograms, and you renewal application requests 3 microcuries. Our conversion of 3 microcuries of U-237 is equal to 0.03675 nanograms. Confirm if you are requesting this small increase in U-237, or if you are using a specific activity that is different than 8.16E4 Ci/g.

d.

RESPONSE: We confirm that we are requesting a small increase in U-237

e. Your current license lists the authorization for depleted uranium (DU) as 10 grams, and you renewal application requests 10 kilograms. Confirm if you are requesting this increase in DU, or if 10 grams is correct.

RESPONSE: We confirm that we are requesting an increase in DU

f. Your current license states that Items BB, 20 kilograms of natural thorium and CC, 20 kilograms of natural uranium, are possessed for storage as waste. Your renewal application states that these items are for research and development, etc. Clarify the use of these materials.

RESPONSE: We use these items for research and development, usually a few grams at a time. We also have some older items and samples in larger quantities that we are storing as waste.

5. The following issues refer to the special nuclear materials requested in Item 5, Radioactive Materials, of your application:

a. Your current license lists the authorization for uranium-233 (U-233) as 25 milligrams, and your renewal application requests 0.4 millicuries of U-233. Our conversion of 0.4 millicuries of U-233 is 41 milligrams U-233. Confirm if you are requesting this increase in U-233, or if you are using a specific activity that is different from 9.75E-3 Ci/g.

RESPONSE: We confirm that we are requesting an increase in U-233

b. Your current license lists the authorization for uranium-235 (U-235) as 10 grams, and your renewal application requests 0.1 millicuries of U-235. Our conversion of 0.1 millicuries of U-235 is 45 grams U-235. Confirm if you are requesting this increase in U-235, or if you are

using a specific activity that is different from 2.19E-6 Ci/g.

RESPONSE: We confirm that we are requesting an increase in U-235

c. Your current license lists the authorization for plutonium (any radionuclide) (Pu) as 200 milligrams total except not more than 5 milligrams plutonium-238 (Pu-238). Your renewal application requests any plutonium radionuclide, 4 millicuries per radionuclide not to exceed 20 millicuries total. The specific activities of the plutonium radionuclides vary by several orders of magnitude. Our conversion of 4 millicuries of Pu-238 is 0.23 milligrams Pu-238 using a specific activity of 17.3 Ci/g; for Pu-239, 4 millicuries is equivalent to 60 milligrams Pu-239 using a specific activity of 6.7E-2 Ci/g. Confirm the limits you need to authorize the uses of plutonium at your site and to cover your current inventory.

RESPONSE: We confirm that 4 millcuries per radionuclide and 20 millicuries total will cover the uses of plutonium at our site and our current inventory

6. Item 7 of your application includes the statement "We request the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license." In accordance with the guidance in NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 11, "Program-Specific Guidance about License of Broad Scope,", confirm that such flexibility will be limited to: training, audits, radiation monitoring instrumentation, material receipt and accountability, safe use and emergency procedures, and radiation surveys; and that other changes will require amendment of your license.

RESPONSE: We confirm that all such flexibility will be limit to: training, audits, radiation monitoring instrumentation, material receipt and accountability, safe use and emergency procedures, and radiation surveys; and that other changes will require amendment of our license

7. The flow chart "Figure 5: Receiving Licensed Materials" in Item 10 of your application, "Material Receipt/Accountability" has a survey performed to confirm that the radiation level on contact with the package does not exceed 200 millirem per hour, before the survey at 3 feet to determine the Transport Index. A good health physics practice would be to approach a suspect package from a distance and perform the survey at 3 feet first, in case dose levels are high enough that caution is needed to make a package contact measurement. No response to this item is required.

RESPONSE: Our current procedure is to take measurements at 1 meter before taking surface measurement. We will correct the error in our procedure's flowchart.

Attachment A

SWIPE REPORT **4/7/2016**

User: Elon Malkin	Instrument: Packard 2550 TR/AB SN 40398
Tray ID: NA	Radionuclide: Ni-63
Vials: 15	Total Activity (uCi): 1.08E-06

Parameter Calculation:		Swipe Area (cm^2):	100
Standard ID:	99307 NI63	Standard (cpm):	170.25
Radionuclide:	Nickel-63	Background (cpm):	24.75
Activity at Reference Date (µCi) :	8.91E-05	Activity at run time (dpm):	198.23
Reference Date:	1/15/2015	Background count time (min):	4
half life (days):	36562	Sample count time (min):	4
Date of run:	4/7/2016	Backgrond counts:	99
Activity at run time (µCi):	8.84E-05	Background activity (dpm):	33.38
		Efficiency (cpm/dpm):	74.1%
		Net Critical Level (net cpm):	5.79
		Lower Limit of Detection (net cpm):	14.28
		MDA (dpm):	19.28
Alpha (α) emitter survey:	no	MDA (nCi):	6.68E-03

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per $100cm^2$ (dpm)	Activity per $100cm^2$ (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per $100cm^2$	22 DPMα per $100cm^2$
1	Lab Space 1	5	22.25	-2.5	-3.37	-1.53E-04	no	no	no	NA
2	Lab Space 2	6	25.5	0.75	1.01	4.60E-05	no	no	no	NA
3	Lab Space 3	7	34.66	9.91	13.37	6.08E-04	no	no	no	NA
4	Lab Space 4	8	25.25	0.5	0.67	3.07E-05	no	no	no	NA
5	Lab Space 5	9	22	-2.75	-3.71	-1.69E-04	no	no	no	NA
6	Lab Space 6	10	26	1.25	1.69	7.66E-05	no	no	no	NA
7	Lab Space 7	11	25.5	0.75	1.01	4.60E-05	no	no	no	NA
8	Lab Space 8	12	24.69	-0.06	-0.08	-3.68E-06	no	no	no	NA
9	Lab Space 9	13	25.25	0.5	0.67	3.07E-05	no	no	no	NA
10	Lab Space 10	14	28	3.25	4.38	1.99E-04	no	no	no	NA
11	Lab Space 11	15	27	2.25	3.03	1.38E-04	no	no	no	NA
12	Lab Space 12	16	24	-0.75	-1.01	-4.60E-05	no	no	no	NA
13	Lab Space 13	17	28.75	4	5.39	2.45E-04	no	no	no	NA
14	Lab Space 14	18	26.25	1.5	2.02	9.20E-05	no	no	no	NA
15	Lab Space 15	19	23.75	-1	-1.35	-6.13E-05	no	no	no	NA

Time: 4.00
Data Mode: CPM Nuclide: MANUAL
Background Subtract: Manual

	LL	UL	LCR	2S%	BKG
Region A:	0.0 -	70.0	0	0.0	0.00
Region B:	0.0 -	2000	0	0.0	0.00
Region C:	70.0 -	1200	0	0.0	0.00

Quench Indicator: tSIE/AEC
Ext Std Terminator: Count
Coincidence Time(ns): 18
Delay Before Burst(ns): Normal

S#	TIME	CPMA	A:2S%	CPMB	B:2S%	CPMC	C:2S%	SIS
1	4.00	170.25	7.66	180.75	7.44	9.75	32.03	84.280
2	4.00	24.75	20.10	38.75	16.06	12.25	28.57	424.90
3	4.00	26.50	19.43	48.75	14.32	20.25	22.22	481.12
1 MISSING TUBE(S)								
5	4.00	22.25	21.20	36.75	16.50	13.00	27.74	488.14
6	4.00	25.50	19.80	42.25	15.38	15.75	25.20	406.58
7	4.00	34.66	16.99	48.25	14.40	12.09	28.76	288.93
8	4.00	25.25	19.90	37.75	16.28	11.50	29.49	346.45
9	4.00	22.00	21.32	31.00	17.96	8.00	35.36	379.49
10	4.00	26.00	19.61	38.00	16.22	10.50	30.86	311.45
11	4.00	25.50	19.80	40.00	15.81	13.00	27.74	393.13
12	4.00	24.69	20.13	36.75	16.50	10.81	30.41	373.29
13	4.00	25.25	19.90	38.75	16.06	10.50	30.86	504.76
14	4.00	28.00	18.90	42.75	15.29	13.50	27.22	427.07
15	4.00	27.00	19.25	50.25	14.11	20.25	22.22	504.56
16	4.00	24.00	20.41	36.50	16.55	11.00	30.15	412.69
17	4.00	28.75	18.65	46.25	14.70	15.25	25.61	480.37
18	4.00	26.25	19.52	42.50	15.34	14.25	26.49	463.43
19	4.00	23.75	20.52	40.00	15.81	14.50	26.26	437.57