



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

August 19, 2016

Brian L. Baker
Center Director, WEAC
Department of Health and Human Services
Public Health Service, FDA
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890-1197

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 591011

Dear Mr. Baker:

This is in reference to your application dated May 17, 2016, requesting to renew NRC License No. 20-08361-01. In order to continue our review, we need the following additional information:

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.
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.
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.
 - 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

B. Baker

- c. 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 chromium-51, gallium-67, selenium 75, technetium 99m, indium-111, 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.
- 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.
- 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.
- 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.
- 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.

B. Baker

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

B. Baker

- 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).
 - 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.
 - 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. 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.
 - e. 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.
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.
 - 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.
 - 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

B. Baker

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.

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.
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.

We will continue our review upon receipt of this information. Please reply to my attention at:

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

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information.

To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5040 or James Cassata at 610-337-5303 or via electronic mail at Elizabeth.ullrich@nrc.gov or james.cassata@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 20-08361-01
Docket No. 030-04675
Mail Control No. 591011

Cc: Edmond J. Baratta, Radiation Safety Officer

To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5040 or James Cassata at 610-337-5303 or via electronic mail at Elizabeth.ullrich@nrc.gov or james.cassata@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 20-08361-01
Docket No. 030-04675
Mail Control No. 591011

Cc: Edmond J. Baratta, Radiation Safety Officer

DOCUMENT NAME: G:\WBL Documents\WBL License RAIL20-08361-01.591011.docx

ML16232A607

SUNSI Review Complete: E. Ullrich

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DNMS	N		N			
NAME	JCassata /JC/	EUllrich /BU/					
DATE	8/19/2016	8/19/16					

OFFICIAL RECORD COPY