UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. STE 210
LISLE, IL 60532-4352

Yun Wang, Ph.D.
Radiation Safety Officer
Indiana University Health/
Central Indiana Cancer Centers
6845 Rama Drive
Indianapolis, IN 46219

DEC 2 2 2016

Dear Dr. Wang:

This refers to the letter dated September 22, 2016, requesting termination of your license no. 13-32241-01. We have reviewed your letter and find that we need the information below in order to continue our review.

We were unable to approve the termination of this license because the information provided was incomplete and insufficient to complete our review. If you wish to pursue this request please provide only one complete, written response to the issues below that is currently dated and signed by a senior management official for this license.

If you have any specific questions concerning this letter or the information we are requesting, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

I think it would be best if, upon receiving and reviewing this letter, you contacted me to arrange a telephone call to discuss these matters and ensure that your response is correct and complete. Information in **bold** font in this letter is intended to emphasize areas in your response that will need specific attention.

Please be reminded that USNRC is an independent and objective federal government regulator.

This is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence.

This is <u>not</u> intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

We cannot authorize licensees to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all *actual licensed materials possessed, used, stored, etc.,* including sealed sources and unsealed materials, spills, and contamination.

If sealed sources were transferred or disposed of as part of the close-out of this location of use, area of use or license, please provide a copy of the final leak test result for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials (such as in 10 CFR 35.100, 35.200 and 35.300) were transferred or disposed of as part of the close-out of this license, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

An assumption of decay for relatively short-lived materials is insufficient to support a termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

Please also be reminded that the "decay-in-storage (DIS)" provisions in 10 CFR 35.92 only apply to materials with a half-life of 120 days or less. For example, this provision may not be used for cobalt-57 sources, among others.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; 10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities," (if you have a medical program; check the "Termination of Activities" section in other volume(s) in the NUREG 1556 series for other than medical programs at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/); "NRC Form 314" at http://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf; and NUREG 1757, Vol. 1, Rev. 2 at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/.

Your complete historical review should specify when and where all licensed materials (such as in 10 CFR 35.100, 35.200 and 35.300) *were actually possessed* under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

If your license historically authorized radioactive materials and/or modalities that you never used, then please so state specifically. Please be mindful that NRC will review your inspection history to corroborate your information.

For licensed materials and waste that were "decayed - in – storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license, such as 10 CFR 35.92 and 10 CFR 2092.

For other licensed material waste streams (only if appropriate), such as incineration (volume reduction), animal carcasses, shipment for burial, compaction, vial disposal, and so on, provide copies of appropriate records to demonstrate "cradle to grave accountability."

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present. For example, please only submit the last, or final, records for leak tests, DIS disposal, etc.

Please respond by stating exactly which licensed materials were used at each authorized location historically and please submit final status survey information covering those radioactive materials.

The final status surveys should consist of: exposure rate measurements to show that all sources of radioactive material have been removed; and, contamination checks (wipe tests) of areas where radioactive materials were used or stored.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/

Please submit the following information with your close-out survey:

a. **Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.**

   Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately. "Counts per minute (cpm)" and similar units are unacceptable.

b. **The name of the person(s) performing the survey.**

c. **The date(s) the survey was performed.**

d. **The instrument(s) used for exposure rate measurements and for analysis of the wipes. It is expected that instruments used will be appropriate for the types of radiation being detected; the exposure rate levels and sensitivity anticipated; and the removable contamination levels and sensitivity anticipated.**

e. **Background readings and each instruments' efficiency or correction factor.**

f. **The date(s) that the survey instrument(s) were last calibrated and the radionuclide(s) each was calibrated with. Please *do not* state when the instrument(s) are "due" to be calibrated in the future. Please *do* state when the instrument(s) were last calibrated.**

g. **The action levels for exposure rate measurements and the action levels and efficiency (cies) for wipe test measurements. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.**

h. **If sealed sources were used in the affected areas/locations, please include a copy of the most recent leak test results for each source. If sources were transferred please provide the license number (if a current Region III NRC licensee) or a copy of the license for the transferee, or a copy of the license and/or permit for the broad scope licensee who took possession of the sources. Appropriate acknowledgment(s) of receipt should be submitted for "cradle to grave" accountability.**

Please always include the telephone number and fax number of at least one person who serves as a point of contact for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.

Please ensure that a senior management representative signs the amendment request. Please ensure that a management representative signs the amendment request, in accordance with 10 CFR 35.12(a), as appropriate, for medical programs.

<u>Signatures Required for Materials Licensing Correspondence and Best Practices</u>

To help ensure that your application for termination (or any other new, amendment or renewal materials licensing request) is complete and may be acted upon by NRC, all incoming licensing correspondence must be physically and legibly signed by an appropriate certifying officer for the materials licensee in question. Signature stamps, electronic signatures, illegible signatures/initials only, etc. are not acceptable.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.

As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all initial requests for licensing requests must be signed, in order to comply with the regulatory requirements listed below.

If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.

All subsequent "new/initial" licensing requests must then be signed appropriately.

Please always sign every licensing document and communication submitted, even if you sign an email and transmit it to us via email/PDF or fax.

Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, may delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:

" (a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,

"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 and the NRC Form 314 require the typed or printed name, position and signature of a certifying officer. The NRC Form 313 can be found at:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead.

The NRC Form 314 can be found at:

https://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf

10 CFR 30.9(a) requires: " (a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:

"(a) An application must be signed by the applicant's or licensee's management."

10 CFR 35.2, "Definitions" states, in part:

"Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates."

Please address all *initial* licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below.

If you are directed to respond to a specific, named reviewer during the review process, then direct your written response to that reviewer by name.

When you are requesting termination of a license, a senior management representative must sign the initial request letter and/or NRC Form 314. In this case, a senior management representative must sign the response letter and NRC Form 314 to request termination of this license. The RSO may co-sign the letter but may not be the sole signatory unless s/he is also a senior management representative and provides the name of his/her management position as well.

In order for us to remove the HDR sealed source and device from your license, if sources were transferred or disposed of please provide a copy of the final leak test result for the sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of the source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current and complete, unredacted copy of its license that clearly shows it is licensed to receive your sources.

If the HDR sealed source was transferred to another appropriately licensed entity or transferred for disposal, and if the HDR source transfer took place within 6 months of the source's receipt under your license, you may be able to use the leak test provided by the vendor that accompanied the source initially. If the transfer took place 6 months or more after it was initially received by you, then a leak test must be performed. Please use 10 CFR 35.67 to conduct the leak test and 10 CFR 35.2067 to prepare the leak test record to be submitted to us.

We were unable to account for the disposal of the co-57 flood source "Cardinal Health/3709.AD.010M.N, SN:1347-183, 0.012mCi on 6/27/16. This source did not appear to have been returned to the vendor.

Your written response should be addressed to my attention at the above address, as "additional information to control number 592009." This will help ensure that your response is processed correctly in our offices.

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-32241-01
Docket No. 030-35383
Control No. 592009