



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

Yuenian (Neal) Zhang, Ph.D.
Radiation Safety Officer
Parkview Health
11141 Parkview Plaza Drive
Fort Wayne, IN 46845

JAN 03 2019

Dear Dr. Zhang:

Enclosed is Amendment No. 127 to your NRC Material License No. 13-01284-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions concerning this amendment 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.

- A. This also refers to several telephone discussions held and emails exchanged between you, your consultant, Sharon Updike, Malinda Gamble, and me on various dates, including December 27, 2018, and January 2, 2019.

Your letter dated July 9, 2018, was the initiating document for this amendment, as a response to several issues I raised in my cover letter to you dated June 19, 2018. You subsequently sent us several other documents and amendment requests, which we included in our review of the July 9, 2018, letter, under control no. 609302. These documents were dated August 16, 2018; December 3, 2018; December 4, 2018; and January 2, 2019.

Unfortunately, we are unable to meaningfully understand the specific requests, format and information in your July 9, 2018, letter, and you and your associates named above told me you preferred to hold a conference call about these matters on January 22, 2019, which we have mutually agreed to.

Since the information in your July 9, 2018, letter is undergoing additional internal review, pending the results of the telephone conference on January 22, 2019, we agreed that I would issue what I can from your subsequent amendment request documents now. All but one of those requests are approved in this amendment and are discussed below.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

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This amendment does not reference or resolve anything requested in the July 9, 2018, letter.

It does remove the location of use at 710 North East Street, Wabash, Indiana (see additional notes about this below).

This amendment adds Shawn Johnson, M.D. and Mitch Travis, M.D. as authorized users for the use of materials in 10 CFR 35.100, 35.200 and 35.300.

This amendment removes authorization for the use of materials in 10 CFR 31.11; and removes David A Trenkner, M.D.; James A. Arata, M.D.; Marvin Dean Dziabis, M.D.; Dean Gifford, M.D.; Randall J. Phillips, M.D.; and Thomas E. Sarosi, M.D. as authorized users.

- B. In correspondence dated August 16, 2018, December 4, 2018, and January 2, 2019, you indicated that you wished to release your former location of use at 710 North East Street, Wabash, Indiana for unrestricted use. The NRC staff has reviewed your final status surveys.

Based on its review, the staff has concluded that all licensable radioactive material has now been removed from your former location of use at 710 North East Street, Wabash, Indiana and residual radioactive material attributable to licensed activities does not exceed current NRC criteria. Based on these conclusions no further remediation or actions with respect to NRC regulated material is required for this location of use and it is suitable for unrestricted use.

Please note, however, that we discovered a discrepancy when comparing your letter dated January 2, 2019, to the information in your letter dated August 16, 2018.

The letter dated August 16, 2018, states that "the area was visually inspected to ensure that all radioactive waste had been removed. No radioactive material was located in the area." The results of the area surveys and wipe tests in the former areas of use at 710 North East Street, Wabash, Indiana were negative, according to the report of the survey performed on June 20, 2018.

Your letter dated January 2, 2019, states that the last date of use for materials in 10 CFR 35.100 and 35.200 was June 18, 2018. The final decay-in-storage record for all residual radioactive waste that was decayed, surveyed and disposed of, according to 10 CFR 35.92 and 35.2092, is attached to this letter.

However, the "Radioactive Waste Disposal" record submitted shows 9 entries of wastes placed into storage after the last date of use on June 18, 2018, through November 26, 2018. For these 9 entries, the dates of final disposal are July 24, 2018 – November 30, 2018.

In your response, please explain how these records appear to document residual radioactive waste at the 710 North East Street, Wabash, Indiana location of use after the specified last date of use, after the close out survey was performed, and contrary to the previous assertions made in the close out survey report. If you wish to discuss this

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matter with me in our January 22, 2019, telephone conference, that would be a welcome and productive activity.

- C. Please also note that, at this time, we were unable to approve Jeff Birn, M.D., as an authorized user for the use of materials in 10 CFR 35.1000, limited to yttrium-90 SIR-Spheres. This is because Dr. Birn's supporting qualification documents do not address the training and experience information in the licensing guidance for this modality, dated February 2016, in section A.3.ii.a. - d. This document is available on our website at: <https://www.nrc.gov/docs/ML1535/ML15350A099.pdf>.

Please respond to this deficiency only with the requested missing information. Please do not resubmit the rest of Dr. Birn's application again. If you wish to discuss this matter with me in our January 22, 2019, telephone conference, that would be a welcome and productive activity.

- D. Since our requests to respond to the issues in Items B and C above should be relatively simple to resolve, within 30 days of the date of this letter (by February 4, 2019), please provide only one complete, written response to these issues that is currently dated and signed by a senior management.

If an alternative timeframe for response is needed please contact me directly.

Your written response should be addressed to my attention at the above address, as "additional information to control number 609302."

Please be sure to accompany/transmit your response with a brief business style letter that identifies your license by name, mailing address and license number; control number as given above; is currently dated; is physically and legibly signed by a senior management representative, in accordance with 10 CFR 35.12(a); is addressed to my attention; and completely resolves the information requested above to continue our review.

Please also be reminded that 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."

- E. As this amendment included a request for expedited action that was not made known to us initially, please refer to the following information that may help you in the future if you should experience other situations when an expedited action is needed. This is not official guidance; it is just some language that I have compiled and used many times over the years to assist licensees in similar situations, to manage their expectations of us and

to help us to help you, our licensees and stakeholders.

"Expedite" Requests:

[For medical licensees only, please take special note of the definitions in 10 CFR 35.2; and the provisions in 10 CFR 35.13 and 35.14; 35.26; 35.24(c); 35.24(d); and, for Type A broad scope medical licenses, 10 CFR 35.49. If your request meets the requirements and/or criteria in these sections, it may be acceptable for you or your Radiation Safety Committee to internally evaluate and approve certain changes to your license and then use the notification processes described in these regulations, as appropriate.

For example, if a medical licensee wants to name an Authorized User (AU) physician to its license who is currently named to another NRC license for the exact same use, the licensee can allow that AU to begin work and utilize the notification process, as permitted by 10 CFR 35.13(b) and (c) and 35.14(a).]

We have noted that many licensees often add the word "expedite" or similar wording to their incoming correspondence, some almost routinely, thus creating an expectation that we will automatically interrupt work on cases already in queue to begin work on the cases requesting non-specific, unjustified and unsupported "expedites."

Others will request an "expedite" after submitting an initial licensing request.

This is disruptive to our process and often such cases contain no other information to justify and support the "expedite" request, nor a date when it is needed by. In addition, these cases are often of poor quality and require more time to review than should be expected.

Therefore, to assist us in serving you better, and in order to serve all of our applicants and licensees fairly, please contact us by telephone ((630) 829-9887, or contact a specific reviewer, if known) if an emergent medical situation or compelling business situation arises after you have submitted an amendment request to your license or new license application and if you can justify and support the need for that particular amendment/new license to be moved up in our normal reviewing queue.

Having this information enables our management to best decide how to handle your expedite request.

Please note that we normally process all licensing actions, including amendment requests, new license applications and renewals, in the order in which they are received, i.e., "first come, first served." We have conducted business in this manner for more than 26 years, as of 2019.

As stated in our acknowledgment card, sent to all who submit licensing applications for our review, the initial review for amendments and new license applications is normally completed within 90 days of receipt, as an internal goal only.

The initial review for renewals is normally completed within 180 days of receipt, again as an internal goal only.

The technical quality of your submission is a primary factor that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Preparing your new license and amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at <http://www.nrc.gov>, will help ensure that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

If you know of a truly emergent medical situation that is unforeseen and beyond the circumstances of your control or a compelling business situation impacting your license and you need a licensing action completed by a certain specific date (not "stat" or "as soon as possible," etc.), please advise us of the particulars of the situation, the specific date when the new license or amendment is needed and the specific justification and support for it, which should be briefly summarized.

Calling us directly is quickest, (630) 829-9500; depending on the situation, email may be useful.

Faxing your application/ request to us at 630-515-1078 is usually the most quick and reliable method of transmission. Only send one, complete, signed and dated application/ request.

Please, under no circumstances, submit more than one copy or other copies by different means of transmission, as doing so introduces errors in processing, delays and confusion.

In addition, please briefly explain why your new license or amendment was not completed and submitted to us at least 90 days prior to the date when you needed it by.

As the volume of non-specific "expedite" requests we receive is quite large, this information is important to determine whether a reasonable effort was, could or should have been made on your part to prepare and submit the request in a sufficiently timely manner to permit our review without passing over the licensing requests of others who made their submissions earlier.

NRC expects the first vetting of all incoming licensing requests to be performed by the requesting licensee/applicant to ensure that the application is complete and accurate in all material respects, which will enable us to more readily assess whether to "expedite" it and act upon it more quickly, with less interference and impact to the cases in queue ahead of it.

Please also ensure that an appropriate senior management official (required by 10 CFR 35.12(a)) and/or your Radiation Safety Officer signs and dates the new license

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application or amendment request letter. For expedite requests, it is preferable that a senior management official sign the request, as possible/appropriate.

Please include the name of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also be helpful in many circumstances.

Please address all licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below, unless you are directed to a specific, named reviewer for the immediate situation only.

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 knowledgeable contact person.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS).

The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-01284-02
Docket No. 030-01593

Enclosure:

Amendment No. 127