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

JUN 07 2019

Erin C. Bell
Radiation Safety Officer
Community Health Network, Inc.
1500 N. Ritter Avenue
Indianapolis, IN 46219

Dear Ms. Bell:

Enclosed is Amendment No. 96 to your NRC Material License No. 13-06009-01 in accordance with your request.

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 other 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.

In the course of this review, we noted that no terminal degree is listed in Condition No. 12.C. for authorized medical physicist Tyler R. Diener. In your next amendment request, please include the terminal degree for Mr. Diener.

This also refers to the telephone discussion between you and me on May 28, 2019, in which we discussed your letters dated February 28, 2019, and May 7, 2019, as well as my letter to you dated July 11, 2018, concerning, in part, the information we need in order to remove authorized materials from your license and/or to remove areas of use and/or locations of use.

Your response letter dated May 31, 2019, contained sufficient information to remove authorization for depleted uranium and americium-241 from your license. Please note that, as a result of this action, Subitem Nos. 6. through 9. I. and J. have been deleted from your license, as they appeared on Amendment No. 95.

Subitem Nos. 6. through 9. K. and L., as they appeared on Amendment No. 95, have been reordered to new Subitem Nos. 6. through 9. I. and J.

In addition, the authorizations in Condition Nos. 10.A., 10.B. and 10.C. were affected by these changes.

Since these sources have been removed and they constituted the last sealed sources authorized by your license that were not subject to 10 CFR Part 35, we deleted Condition No. 13 from your license at this time. Your remaining sealed sources are all still subject to 10 CFR Part 35, including, but not limited to, the inventory and leak test requirements.

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

Former Condition No. 14 is now Condition No. 13.

Condition Nos. 13.S., 13.T. and 13.U. were added to your license to, incorporate the addition of your new low level waste room area of use and account for the removal of depleted uranium and americium-241 from your license.

These actions resolve Items 1, 2 and 4 in your letter dated February 28, 2019, and Item 3 in your letter dated May 31, 2019.

However, we excluded Item 3 in your letter dated February 28, 2019, and Item 1 in your letter dated May 31, 2019, from Condition Nos. 14.S. and 14.U. because the information provided in these letters was insufficient to completely support the release for unrestricted use of the hot labs at 1500 North Ritter Ave., Indianapolis, Indiana.

In a telephone call between you and me on July 11, 2019, you mentioned that you would soon be relocating certain areas of use to a new hospital section and afterwards, you would need to decommission the current/old areas of use for unrestricted use and eventual demolition.

To assist you, we included comprehensive language in our letter to you dated July 11, 2019, as decommissioning advice language I've compiled and used many times over the years.

We discussed this information again on May 28, 2019, in the context of the requests made in your letter dated February 28, 2019, which was lacking several key pieces of information.

After reviewing your response letter dated May 31, 2019, we noted that some information was still lacking regarding the release of the two hot labs.

I sent you an email and attempted to schedule a telephone call with you to discuss this missing information on June 4, 2019, and you responded in an email on June 5, 2019, that you would be unable to schedule a call. You requested that we transmit the missing information request in writing.

Therefore, I partially issued your requests in this amendment and this letter will transmit again the information we need.

Please provide only one complete, written response that is currently dated and signed by a senior management representative.

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

Please do not resubmit any information beyond the scope of our specific requests, such as if you were to resubmit your letters in entirety again. Resubmitting in entirety, unless we request it, often delays the progress of our review without benefit to your licensed program.

Your written response should be addressed to my attention at the above address, as "additional information to control number 611618."

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; is addressed to my attention; and completely resolves the information requested above to continue our review.

To remove areas of use from a license:

1. Start with a master list of every type of authorization/radionuclide that has ever been authorized for the areas of use in question, even those that have already been taken off before, if any. This is an historical review.

   You have already described the materials used in the hot labs that were previously deleted from the license. You do not need to repeat this part of the historical review.

   However, please tell us which materials and/or types of use were authorized in each of the hot labs prior to their shutdown and decommissioning.

2. Tell us explicitly which of these authorizations you ever actually used (as in possessed, stored, handled, used, etc.) and when did you stop using each authorization, as in a date (month and year minimum) for each area of use, i.e., each hot lab.

   We still do not have this information. An approximate date (month and year) when use was discontinued for each authorization/radionuclide in each hot lab is helpful for providing context in consideration of your request to remove these areas of use.

3. If you did not use any licensed radionuclides and/or authorization(s), tell us that explicitly also. Bear in mind that we will corroborate your responses with your inspection and enforcement history in our records.

   For example, if both of your hot labs was authorized for the receipt, use and storage of materials in 10 CFR 35.400 but you never used that authorization in one of the hot labs, tell us that and specify which hot lab was not used for that purpose.

4. For those authorizations that you used, you must account for each "from cradle to grave." In other words, you have to describe what you used and where (locations of use, areas of use, storage, etc.); prove that there is no residual leakage, if sealed sources were involved; prove that there is no residual, removable contamination; prove that all materials have been decayed, if allowed; prove that all materials have been disposed of to authorized/licensed entities, received by them and acknowledged by them; provide copies of Agreement State license(s) for those recipient entities licensed by Agreement States, as NRC does not have access to these licenses to verify their licensure.

   Were there any spills, leakage and/or contamination incidents in these hot labs?

   Your letter dated "February 28, 2019, states "All radioactive materials have been moved to the new Nuclear Medicine suite, which was added to our license on Amendment 95."

Please describe the materials that were moved to the new Nuclear Medicine suite, such as sealed sources, unsealed sources, radioactive waste undergoing decay-in-storage under 10 CFR 35.92, radioactive therapy materials (residual 10 CFR 35.300 wastes, 10 CFR 35.400 seeds, 10 CFR 35.600 HDR source), etc.

Were there any sealed sources possessed, used and/or stored in these hot labs? If so, please provide the last leak tests performed on these sources prior to transfer.

Were these sources moved to the new Nuclear Medicine suite? A "before" and "after" inventory for the sealed sources transferred would be helpful.

We still do not have this information. Please provide it.

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.

Your letter dated February 28, 2019, included a request for an "expedited review" as "the areas .....are in an area that needs to be demolished as soon as possible."

Please note the following for future use should you need to request an "expedited review" again:

"Expedite" Requests:

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); and 35.24(d). 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."

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 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 25 years, as of 2018.

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) 829-9887; 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. Do not 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 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.

Please 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."

If you have any questions, please contact me directly at 630-829-9841. My fax number is 630-515-1078 and my email address is colleen.casey@nrc.gov."

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.

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

Colleen Carol Casey
Materials Licensing Branch

License No. 13-06009-01
Docket No. 030-01625

Enclosure:
Amendment No. 96