



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210

FEB 21 2017

Carey Unthank, PharmD
Radiation Safety Officer
c/o Craig Kinne
Corporate Radiation Safety Officer
Triad Isotopes, Inc.
4205 Vineland Road
Suite L1
Orlando, FL 32811

Dear Messrs. Unthank and Kinne:

Enclosed is Amendment No. 7 to your NRC Material License No. 09-32781-01MD in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

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.

This also refers to telephone and email contacts, including a telephone contact on February 9, 2017, I have received about this license recently from Neal Stubbs, who is not listed on this license or referenced in any capacity.

Please explain who Mr. Stubbs is in relation to this license and advise us clearly in writing as to whether he is a point of contact for this license. We are asking for this information to protect the integrity and security of your NRC license.

If Mr. Stubbs should not be contacting us, please advise him to refrain from doing so.

Please note that we were unable to approve John Vardsveen, PharmD, BCNP, as an Authorized Nuclear Pharmacist (ANP) at this time because the information provided in your letter dated November 17, 2016, was insufficient to complete our review.

If you wish to pursue this authorization, please correct the missing information and submit it to us as a written response, addressed to my attention as "additional information to control number 592404."

Dr. Vardveen's application failed to include evidence of compliance with 10 CFR 35.55(a) and 35.55(b)(2). Since no actual copy of his BCNP certificate was included and no appropriately prepared, signed and dated preceptor attestation was included, the documents supporting Dr. Vardveen's application were incomplete.

The following is information you may find useful in preparing this response and future licensing correspondence.

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 with our licensees to achieve an improved working understanding of our respective roles in the licensing process.

This is not 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.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information," ..."(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."

What 10 CFR 30.9(a) means, in part, is that you, as the licensee, are primarily responsible for the quality of your submissions to NRC, as well as the completeness and accuracy of all information provided.

You, the licensee, are responsible for checking and verifying that the information you provide supports the requests you make to your license and that the requests you make to your license are in alignment with our regulations and guidance.

Please do not expect NRC to perform the first check and verification of your licensing requests. We perform the regulatory authority verification that the information needed to consider your requests has been completely provided.

It is understandable and expected that, occasionally, some minor additional information must be solicited from a licensee in the course of the review process.

But such occurrences should be rare and exceptional and address primarily minor issues, information that could not have been foreseen or planned around, etc.

It should not be routine and addressing basic issues that have been codified in our regulations for many years and which have been discussed in ample detail in our guidance documents, regulatory issue summaries, information notices, information on our website, and brought to your attention in previous deficiency and cover letter correspondence.

Your assistance in these matters is greatly appreciated and enables us to serve you, and all of our licensees and applicants, better and in a more timely fashion.

We also made some minor spelling and format adjustments to your license at this time, including the addition of language missing from Condition No. 15.

Condition No. 16, as it appeared on Amendment No. 6, was deleted at this time, in favor of referencing 10 CFR Part 71 in the Preamble language at the top of page 1 of your license.

We also noticed that most of your Authorized Nuclear Pharmacists (ANPs) are listed on the license without the identity of their terminal degree and/or registration. Dr. O'Connor was added as an ANP in this amendment with his terminal degree included in Condition No. 12.B.

It is a good practice to include terminal degrees and/or registrations for your ANP's, in order to differentiate among individuals with similar names, as well as to acknowledge the required credential for an ANP. Please provide the terminal degrees and/or registrations for all ANP's listed on this license in a subsequent amendment.

We first brought this matter to your attention in the letter transmitting Amendment No. 03 dated July 9, 2014 but apparently nothing has been done to date.

Please contact me at (630) 829-9841 or (800) 522-3025, ext. 9841 if you have any questions. My fax number is (630) 515-1078.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>.

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.

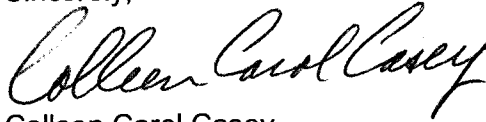
You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

C. Unthank

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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,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 09-32781-01MD
Docket No. 030-38276

Enclosure:

Amendment No. 7