



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. STE 210
LISLE, ILLINOIS 60532-4352

Lynda Donegan
Vice President/Professional Health Services
Truman Medical Center
Department of Radiology
2301 Holmes St.
Kansas City, MO 64108

MAY 14 2019

Dear Ms. Donegan:

- A. This refers to your letter dated March 11, 2019, ("the letter") requesting a change in Radiation Safety Officer ("RSO") from Lawrence Ricci, D.O. to Sebastiano Anzalone, CNMT. We have reviewed your letter and we find that we will need additional information as follows:
1. It appears that Mr. Anzalone is already named RSO on at least one other license presently, according to the statement made in your letter that you included in 1.c. "Radioactive Materials License #01-59-01, verifying Mr. Anzalone's as a current Radiation Safety Officer for a Non-Medical RAM License."

However, a copy of "Radioactive Materials License #01-59-01" was not included with your letter so we have no way of knowing what is being referred to here.

Please provide a copy of this license.

Please also note that being named as RSO for a non-medical use license does not qualify Mr. Anzalone to become the RSO on a medical use license.

It does tell us that Mr. Anzalone may also be currently named as RSO on other medical or non-medical licenses, in NRC and/or Agreement States.

Please tell us specifically of the total number of licenses, medical and/or non-medical, in NRC and/or Agreement States, on which Mr. Anzalone is currently named RSO.

2. Please describe how Mr. Anzalone will be able to devote sufficient time to this license to carry out the RSO duties, given his other RSO responsibilities.
3. Please describe the minimum amount of time Mr. Anzalone expects to spend serving onsite as RSO for this license over a specified time period, such as "per week" or "per month."
4. Please specify what Mr. Anzalone's typical response timeframe would be if he should be needed for emergency response for this license.

5. Your letter did not provide the name, telephone number, fax number and email address of at least one knowledgeable person for us to contact about this amendment request. Please provide this information in your written response.
6. 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.”

Please submit a written response to the information above and below, within 10 days of the date of this letter (by May 24, 2019, close of business) or contact me to make alternative arrangements.

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as a business-style letter, containing complete identifying information for your license.

Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us.

Please do not email a PDF document to us, and transmit a faxed version, and/or a hard copy sent by mail.

Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors.

Please address your written response to my attention as “additional information to control number 611578” to facilitate proper handling in our offices.

Please respond directly to me for this case only; future new licensing requests should be addressed to the "Materials Licensing Branch Chief." Upon receipt of your written response we will continue our review.

- B. We noted that your letter was marked “URGENT” and that you requested it be “expedited,” although no date when it was needed or justification or support for the expedite request was indicated. Simply marking something to us as “urgent” and/or asking us to “expedite” it is insufficient, unacceptable and unfair to the licensees who submit their amendment requests without such expectations and in a timely manner.

In your written response now, and if or when you request expedited reviews in the future, please provide complete answers to the following information. This is not official guidance but it is compiled from a great many expedite requests we’ve received over the years. It is only a summary of language I have had to use often in deficiency correspondence, or “requests for additional information.”

“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."

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 sub-optimal or even 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 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 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 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 and, perhaps, more accurately and completely.

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 application or amendment request letter.

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

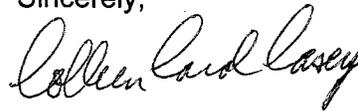
Please include the name of at least one knowledgeable contact person who is familiar with your new license application or amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. A business email address for the contact person may also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

In the future, 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.

If you have any questions or comments please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

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,

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

Colleen Carol Casey
Materials Licensing Branch

License No. 24-25816-01
Docket No. 030-30130
Control No. 611578