

REQUEST
FOR
ADDITIONAL INFO.



NOV. 27, 2018

Colleen Carol Cary

to be scanned in
as PDF + emailed
to Carlson.

11-27-18

~~Official Use Only - Security-Related Information~~

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

AUG 28 2018

Do NOT
RESUBMIT ANYTHING
OTHER THAN WHAT IS
NOTED BELOW.

Dan H. Marshall, DVM
Radiation Safety Officer
Cats Radio - Iodine Treatment Centers
70 Gallup St.
Mount Clemens, MI 48043

USE C/N 610266
FOR RESPONSE

Dear Dr. Marshall:

Enclosed is Amendment No. 24 to your NRC Material License No. 21-26539-01 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.

Your application dated May 30, 2018, requested the new authorization of Marisa Verwys, DVM, Lauren E. Demos, BVMS Hons, and Toni Brooks, DVM as authorized users. We were unable to approve any of these individuals as authorized users (AUs) because your application dated May 30, 2018, contained information that was insufficient to complete our review.

If you wish to pursue these matters, please provide only one complete, written response that is currently dated and signed by a senior management official for this license. This will help ensure that your response is processed correctly in our offices.

Your written response should be addressed to my attention at the above address, as "additional information to control number 608945." We will then continue our review.

NOT
DONE
NEEDED

A. Please identify the names of the institutions granting each proposed AU the terminal degree attributed to each; specify the dates when these degrees were conferred; and please explain what is meant by the degree "BVMS Hons" for Lauren E. Demos, as we are unfamiliar with this degree. Is this degree from an accredited institution, is it a degree in veterinary medicine, and is it a doctoral degree?

B. Please describe each proposed AU's "hands-on" use of iodine-131, separately for each proposed AU by name, including dates of use, tasks performed (e.g., dose calculation, dose preparation, dose administration, area surveys, familiarity with emergency and spill procedures, etc.

C. Please break out each proposed AU's training, separately for each proposed AU by name, in radiation protection principles, characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards

COPY
OF
DIPLOMA
IS TOO
DARK
TO
READ -
NEED
MUCH
BETTER
COPY

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

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of exposure to radiation. Are these proposed AUs familiar with NRC's regulations and terms of the license?

D. The following discrepancies and issues were noted during this review. Please explain each discrepancy and submit a written response to specifically and clearly resolve each one:

1. The application dated May 30, 2018, shows, in Item 2, the name of this license as "Cats Vets - Dr. Dan Marshal" at the 70 Gallup St., Mount Clemens address and zip code as 48043. The letterhead used for the letter dated June 8, 2018, attached to the application dated June 11, 2108, still says "Cats Radio - Iodine Treatment Center" but no address is included on the letterhead to verify the current zip code. Has the name for this license changed? Has the spelling of Dr. Marshal's last name changed? Has the zip code for this license changed?
2. The application dated June 11, 2018, shows, in Item 2, the name of this license as "Cats" at the 70 Gallup St. Mount Clemens address and zip code as 48036. Has the name for this license changed from what we currently show it as, and/or from the name questioned in D.1. above?
3. On the letter dated May 24, 2018, attached to the application dated May 30, 2018, Dan H. Marshall, DVM's signature indicates he is the "Radiation Safety Officer." He is not the Radiation Safety Officer for this license. Please explain.

NOT
ADDRESSED
IN
RESPONSE -
NEEDED

E. Neither of the applications dated May 30, 2018, or June 11, 2108, mentioned a date when these licensing actions were needed by. However, I received several phone calls and emails from you requesting that these applications be completed prior to early August. A specific date in August was not provided and, aside from saying that one of the doctors was going on sabbatical, no meaningful support for the expedite request was shared with us, although I requested as much in my email to you dated August 2, 2018.

The following information may assist you in preparing future licensing requests.

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." Or they call us after sending in a licensing request and say they want their amendment "expedited."

This is disruptive to our process and often such cases contain no other information to justify and support the "expedite" request, nor a specific 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

ONLY FAX
COVER SHEET
MENTIONS
DATE NEEDED
SHOULD BE IN
ACTUAL LETTER,
IF POSSIBLE;

MY LETTER TO
MARSHALL WAS
DATED 8/28/18;
WE RECEIVED
YOUR LETTER
OCT. 22, 2018, AND
IT IS INCOMPLETE.
PLEASE ENSURE
COMPLETE AND
ACCURATE WORK AND
ALLOW US AT LEAST 90 DAYS
FOR REVIEWS.

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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) 829-9500; 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. 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

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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.

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.

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).

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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
Materials Licensing Branch

License No. 21-26539-01
Docket No. 030-33367

Enclosure:
Amendment No. 24