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

NOV 15 2017

Thomas J. Moenster
Radiation Safety Officer
Missouri Baptist Medical Center
3015 N. Ballas Road
St. Louis, MO 63131

Dear Mr. Moenster:

Enclosed is Amendment No. 89 to your NRC Material License No. 24-11128-02 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, which is also the fastest way to transmit amendment requests and responses to requests from us for additional information. My email address is colleen.casey@nrc.gov, which should not be used transmit amendment requests and responses to requests from us for additional information, unless previously arranged with me personally.

A. We were unable to approve any of the new requests in your letter dated August 18, 2017, to add new authorization for yttrium-90 SIRSpheres, as permitted by 10 CFR 35.1000. Your request included the addition of 2 proposed authorized users (AUs), John Karageorgiou, M.D. and Randall Heller, M.D., for the use of materials in 10 CFR 35.100, 35.200, 35.300 and 35.1000, which appeared to be limited to yttrium-90 SIRSpheres. You also requested to add Cody J. Morris, M.D. and Gerald Palagallo, M.D. as AUs for the use of materials in 10 CFR 35.100, 35.200 and 35.300.

   This also refers to the telephone discussions between you and me concerning the qualifications to use yttrium-90 SIRSpheres for Drs. Karageorgiou and Heller on October 2, October 3, and October 5.

   We were unable to approve any of these four physicians as AUs for any of these modalities at this time because the information in your letter dated August 18, 2017, was insufficient to complete our review.

   If you wish to pursue these authorizations, please provide only one response to the items below. Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a. Please ensure that the requested information is answered completely and accurately.

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

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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 600483" to facilitate proper handling in our offices.

1. Dr. Karageorgiou's application to become an AU failed to include:

   a. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which he is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

   b. Evidence that his training and experience complied with 10 CFR 35.290(c)(1) and 35.290(c)(2).

   c. The name, terminal degree and qualifications of the person(s) who supervised his training and experience, as this information is not described in the documents supporting his request.

   d. Clarification as to which subsections of authorization under 10 CFR 35.300 that Dr. Karageorgiaou is applying for. We cannot approve any new AU for all of 10 CFR 35.300 because there is no actual medical modality for 10 CFR 35.390(b)(1)(ii)(G)(4). Therefore, all new requests to become an AU must explicitly state which subsections are being applied for, such as 10 CFR 35.392, 35.394 and/or 35.396.

   e. The license that his apparent preceptors, Barry A. Siegel, M.D. and Jennifer E. Gould, M.D., from Washington University worked under is a Type A broad scope license and as such, it does not include the names of AUs on the license itself. The licensee's internal Radiation Safety Committee (RSC) evaluates and approves or disapproves of AUs and maintains records of AUs. No information was provided to demonstrate that either Dr. Siegel and/or Dr. Gould were AUs under the Washington University license and qualified to serve as preceptors for Dr. Karageorgiou.

   f. Your letter stated that Dr. Karageorgiou wanted to become an AU, in part, for "10 CFR 35.1000." However, there are several different emerging technologies regulated under "10 CFR 35.1000." Since you applied only for the emerging technology of yttrium-90 microspheres, we assumed that is the only modality you wanted Dr. Karageorgiou to be considered for. Please confirm whether our understanding is correct and in the future, please explicitly state which emerging technology under 10 CFR 35.1000 is being applied for.

g. From the information provided, it appears that Dr. Karageourgiou has not met the qualifications in the yttrium-90 microspheres guidance under sections A.1, A.2. or A.3.ii.

Please refer to the regulatory requirements stated above and the appropriate sections in NUREG 1556, Vol. 9, Rev. 2, especially Appendices B, D and E, for assistance in preparing your written response. In particular, Part II on page D-6, paragraph one and Section V. on page D-3, second paragraph in Appendix D reference some of the information we are requesting and describe preceptor statements and supporting licenses for preceptors. The following links may be helpful:

http://www.nrc.gov/materials/miau/med-use-toolkit.html

http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

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."

You may also find it beneficial to review NRC Information Notice 2007 – 38: "Ensuring Complete And Accurate Information in the Documentation of Training and Experience For Individuals Seeking Approval As Medical Authorized Users," which is located on our website at:

http://pbadupws.nrc.gov/docs/ML0722/ML072270127.pdf

This IN explains the importance and necessity of compliance with 10 CFR 30.9 and the potential consequences of non-compliance.

2. Dr. Cody Morris' application failed to include:

   a. Whether Dr. Morris is a male or a female. This is because one of the letters submitted for Dr. Morris uses the word "her" and the other letters use the word "him" to describe Dr. Morris.

   b. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which he is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

c. Evidence that Dr. Morris' training and experience met 10 CFR 35.290(c)(1)(i)(A) for "instrumentation;" and 10 CFR 35.290(c)(1)(ii) and 35.290(c)(2), the latter because we cannot clearly identify and verify Dr. Morris' preceptors and supervising individuals.

d. The license that Dr. Morris' preceptors worked under, Emory University, is an Agreement State license that NRC does not have jurisdiction over. In addition, it is likely a Type A broad scope license, so, as described above, it does not list AUs on the license.

Please submit a complete, current, unredacted copy of the license for Emory University that shows it is authorized for the materials that Dr. Morris is seeking authorization for and either the name(s) of Dr. Morris' supervising person(s) and preceptors on this license as AUs for these materials or a signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that Dr. Morris' supervising person(s) and preceptors were AUs. This letter must also specify the timeframe when the supervising person(s) and preceptors served as such for Dr. Morris.

e. Please refrain from submitting extraneous documents that do not support the requested authorizations, i.e., information about training and experience with mammography interpretation that Dr. Morris had or the letter acknowledging completion of residency. In addition, the letter stating that Dr. Morris had passed the Core Exam for the American Board of Radiology added no substantive or meaningful information to support Dr. Morris' requests. Either a physician is certified by a medical specialty board that we recognize for what s/he wants to become an AU for, in conjunction with the required regulatory parameters, or not. It appears that, at this time, Dr. Morris is not so certified.

3. Dr. Randall Heller's application failed to include:

a. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which he is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

b. Evidence that his training and experience complied with 10 CFR 35.290 and the appropriate subsections described in d. below, 10 CFR 35.392, 35.394 and/or 35.396.

c. The name(s), terminal degrees and qualifications of the person(s) who supervised and preceptored his training and experience, as this information is not described in the documents supporting his request.

d. Clarification as to which subsections of authorization under 10 CFR 35.300 that Dr. Heller is applying for. We cannot approve any new AU for all of 10 CFR 35.300 because there is no actual medical modality for 10 CFR 35.390(b)(1)(ii)(G)(4). Therefore, all new requests to become an AU must

explicitly state which subsections are being applied for, such as 10 CFR 35.392, 35.394 and/or 35.396.

e. Who Dr. Heller's supervising individual(s) and preceptor(s) were, the license they worked under, the modalities they were qualified as AUs for and the timeframes when they served as supervising individual(s) and preceptor(s).

f. Your letter stated that Dr. Heller wanted to become an AU, in part, for "10 CFR 35.1000." However, there are several different emerging technologies regulated under "10 CFR 35.1000." Since you applied only for the emerging technology of yttrium-90 microspheres, we assumed that is the only modality you wanted Dr. Heller to be considered for. Please confirm whether our understanding is correct and in the future, please explicitly state which emerging technology under 10 CFR 35.1000 is being applied for.

g. From the information provided, it appears that Dr. Heller has not met the qualifications in the yttrium-90 microspheres guidance under section A, with the possible exception of A.3.i.b. Since we have no information about Dr. Heller's specific, relevant training and experience or whether and how his work was "supervised," we cannot conclusively acknowledge that he meets A.3.i.b.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

We noted that patient records were included with Dr. Heller's application; kindly refrain from submitting such protected information as it fails to support your requests and it is unnecessary.

4. Dr. Gerald J. Palagallo's application failed to include:

a. The name of the State, Territory, or Commonwealth of the United States or District of Columbia in which he is licensed to practice medicine, pursuant to 10 CFR 35.2, "Definitions," for the word, "Physician."

b. Evidence that his training and experience complied with 10 CFR 35.290 and the appropriate subsections described in d. below, 10 CFR 35.392, 35.394 and/or 35.396.

c. The name, terminal degree and qualifications of the person(s) who supervised and preceptored his training and experience, as this information is not described in the documents supporting his request.

d. Clarification as to which subsections of authorization under 10 CFR 35.300 that Dr. Palagallo is applying for. We cannot approve any new AU for all of 10 CFR 35.300 because there is no actual medical modality for 10 CFR 35.390(b)(1)(ii)(G)(4). Therefore, all new requests to become an AU must

explicitly state which subsections are being applied for, such as 10 CFR 35.392, 35.394 and/or 35.396.

e. Who Dr. Palogallo's supervising individual(s) and preceptor(s) were, the license they worked under, the modalities they were qualified as AUs for and the timeframes when they served as supervising individual(s) and preceptor(s).

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

We noted that patient records were included with Dr. Palagallo's application; kindly refrain from submitting such protected information as it fails to support your requests and it is unnecessary.

B. Please be reminded that USNRC is an independent and objective federal government regulator.

The following is not official guidance, it is only a summary of language I have had to use often in deficiency correspondence.

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.

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

In preparing your response, 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 this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved. Only after the request has been thoroughly vetted by the applicant/licensee should the licensing correspondence be transmitted to NRC. This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

In this instance, after submitting your original request letter, you then requested an expedited review. Your request for an expedited review was initially unspecified, unjustified and unsupported. Subsequently you re-focused the parameters of the review to scale it down, and then offered information to justify and support the expedite request. For future expedite requests, should they become necessary, the following information may help you.

"Expedite" Requests:

A request to "expedite" a licensing action should be a rare and occasional occurrence normally due to circumstances beyond your control, unforeseeable emergencies, sudden medical issues pertaining to the delivery of care to patients, compelling business situations that could not have been planned around, and so on.

To assist us in serving you and all of our licensees more efficiently, please contact us by telephone if a circumstance such as those above arises before (best whenever possible), or after you have submitted an amendment request to your license, or new license application, and if you can unambiguously justify and support your asserted need for that particular amendment 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."

As stated in our acknowledgment card, sent to all applicants and licensees who submit correspondence 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, as an internal goal only, is normally completed within 180 days of receipt.

The technical quality, accuracy and completeness of your submission are primary factors that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Please note that your submission should not include extraneous documentation, which only serves to delay the review process.

Please only submit information that our regulations and guidance specifically address. Please completely and concisely answer questions that we ask and provide information that we specifically request.

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 greatly help ensure

that your correspondence is complete and accurate in all material respects, as 10 CFR 30.9 (a) requires it to be.

Ideally, if you know of an emergent medical situation or 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.

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.

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.

Signatures Required for Materials Licensing Correspondence and Best Practices

The following information is provided for reference "as needed."

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.

As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all initial requests for licensing requests must be signed, in order to comply with the regulatory requirements listed below.

If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.

All subsequent "new/initial" licensing requests must then be signed appropriately.

Please always sign every licensing document and communication submitted.

Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, may delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:

" (a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,

"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 requires the typed or printed name and signature of a certifying officer. The NRC Form 313 can be found at:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead.

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."

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:

"(a) An application must be signed by the applicant's or licensee's management."

10 CFR 35.2, "Definitions" states, in part:

"Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates."

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. 24-11128-02
Docket No. 030-08325

Enclosure:

Amendment No. 89