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

MAR 11 2019

Alan S. Jackson, M.S., CHP
Radiation Safety Officer
Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038

Dear Mr. Jackson:

Enclosed is Amendment No. 70 to your NRC Material License No. 21-11850-01 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.

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.

A. We were unable to approve Newton Hurst, M.D. as an authorized user for the use of materials in 10 CFR 35.600, limited to iridium-192 in a high dose rate (HDR) device, because the information supporting his application, as described in greater detail below, was insufficient to complete our review.

   If you wish to pursue this authorization, please provide only your response to the items below in A 1 – 3 and B 1 – 5.

   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, with attached supporting information, as appropriate.

   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 611470" to facilitate proper handling in our offices.

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

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This refers to your unsigned letter ("the letter") dated February 5, 2019, attached to the NRC Form 313 application ("the application") dated January 23, 2019, and signed by Denise Brooks-Williams, Vice President and CEO for Henry Ford Macomb Hospital, concerning an amendment request for your NRC Material License No. 21-11850-01. These documents were received in our offices on March 1, 2019.

The letter stated that you requested an expedited amendment to this license to add two individuals for medical staffing issues and that adding Newton Hurst, M.D. "as soon as possible" is a "critical need."

Dr. Hurst has applied to become an authorized user (AU) for the use of materials in 10 CFR 35.600, limited to iridium-192 in a high dose rate (HDR) remote afterloading brachytherapy device.

We also noted that you have one location of use on this license for the use of the HDR device and you already have 12 AUs listed on this license for the use of the HDR device. Your most recent inspection was on March 7, 2018, and we found that you were conducting approximately 100 HDR treatments per year.

The other proposed AU, Parag J. Parikh, M.D., applied to become an AU for the uses of materials in 10 CFR 35.300 and 35.600, limited to iridium-192 in an HDR device. Dr. Parikh supported his application with credentials demonstrating that he has already been an AU for these same uses for many years as a permittee under a Type A medical broad scope license.

His qualifications are acceptable under 10 CFR 35.13, 35.14 and 35.59 and he has been added to the license as your 13th AU for the use of materials in 10 CFR 35.600, limited to iridium-192 in an HDR device.

We noted that your letter did not indicate that adding Dr. Parikh to the license needed to be done "as soon as possible" for a "critical need," as was the case with Dr. Hurst.

Please review the following information and, in your written response, advise us further about your request for this "expedited" amendment, in light of the above.

1. On the NRC Form 313A (AUS) submitted for Dr. Hurst, under "Requested Authorizations," both 10 CFR 35.400 for manual brachytherapy and 35.600 for remote Afterloader units are affirmatively designated.

   However, your letter only requested that Dr. Hurst be considered for the use of materials in 10 CFR 35.600, limited to iridium-192 in an HDR device. Please explain this discrepancy and confirm your intentions for his authorization.

2. In Part I, section 3.a. of the NRC Form 313A (AUS) for Dr. Hurst, the table of classroom and laboratory training is filled out and 40 clock hours are listed for each of the 4 topical areas, which totals 160 hours.

However, the total hours of training listed on the form is "200 hours" and "200 hours" is the required minimum number of hours in these topics under 10 CFR 35.490(b)(1)(i) and 35.690(b)(1)(i).

Please submit additional documentation that accounts for Dr. Hurst's training in the remaining 40 hours of required training. A current supervising individual, etc., preceptor signature and current dates for this training will also be necessary, as required by the regulations above.

This discrepancy/shortage of training hours is also reflected in Part II, Second Section of the NRC Form 313A (AUS) under "Training and Experience" for Dr. Hurst. Please correct this issue also, including a current preceptor signature and current date for the additional training hours.

3. In Part II, Fifth Section of the NRC Form 313A (AUS), the preceptor, Steven R. Miller, M.D. appears to have signed this form on December (indecipherable day) in what appears to be "13," for 2013. In addition, Dr. Miller's signature is barely legible.

   Since Dr. Hurst's training and experience under Dr. Miller took place from "7/1/2012 to 6/30/2016," it does not seem logical or correct that Dr. Miller could or should have signed this form approximately 2 ½ years before the completion of Dr. Hurst's training.

   Please explain this situation and, as appropriate, obtain currently and completely dated and correctly signed forms for Dr. Hurst.

B. As you requested that this amendment request be expedited and as the justification and support for the request was inadequate, please note the following information and, in your response to add Dr. Hurst, please address the items below.

   "Expedite" Requests:

   This is not official guidance. This is instructive general advice and language that I have developed over many years to use for instances such as this because they occur so often.

   [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); 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 little or no other information to meaningfully justify and support the "expedite" request, nor a specific date when it is needed by.

In addition, these cases are often of suboptimal 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 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/response 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 or inadequately supported "expedite" requests we receive is significant, this information is necessary 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.

With these considerations, please include the following information in your response:

1. Please state the specific date (month, day and year) when you need this amendment completed to add Dr. Hurst.

2. Please explain why the 13 AUs already on this license are unable to meet your needs for the delivery of care such that only a new, not-yet-approved AU must be relied upon for this purpose.

3. Please state and describe briefly what the "critical need" is that is referred to in your letter to add Dr. Hurst to the license. Please explain in more clear and specific terms why you have requested an "expedited" review.

4. It appears that your request began on January 23, 2019, with the NRC Form 313 application signed by Ms. Brooks – Williams; continued on February 5, 2019, with the preparation of the unsigned letter; and these documents were subsequently received in our offices on March 1, 2019, 36 days later.

The preparation time factor should be considered when requesting an "expedited" amendment. Please explain briefly how the apparent delays in the preparation of your amendment justify moving your review to the front of our queue over many other licensees whose submissions were received weeks, even months earlier.

5. Please briefly explain why your amendment request was not submitted to us at least 90 days prior to the date when you needed it by.

6. No response item – 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 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 "Agencywide Documents Access and Management 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. 21-11850-01
Docket No. 030-02106

Enclosure:

Amendment No. 70