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

FEB 28 2017

Mark Beanblossom
Radiation Safety Officer
Good Samaritan Hospital
520 South 7th Street
Vincennes, IN 47591

Dear Mr. Beanblossom:

Enclosed is Amendment No. 82 to your NRC Material License No. 13-01787-01 in accordance with your request.

1. **This amendment removes authorization for iridium-192 high dose rate remote afterloading brachytherapy (HDR) from your license and approves you, Mark Beanblossom, as the new Radiation Safety Officer (RSO). The authorization for Dr. Furman no longer includes HDR in Condition No. 12.B.**

   Dr. Yinghui Zhang has been removed as the RSO and, since HDR has been removed, your license no longer authorizes Dr. Zhang, or anyone, as an Authorized Medical Physicist (AMP).

   We also deleted Condition No. 13 from your license at this time in favor of referencing 10 CFR Part 71 in the Preamble language at the top of page 1 of your license. The subsequent Condition has been re-numbered as a result.

2. **Subitem Nos. 6. – 9.G. of your license authorizes two strontium-90 sealed sources for storage only, incident to disposal.**

   We asked you about this authorization in our letter to you, addressed to the then-RSO Dr. Zhang, dated August 17, 2015, and reminded you then, as now, that since the half-life of strontium-90 exceeds 120 days, it may not be disposed of under the "decay-in-storage" provisions in 10 CFR 35.92. So it may not be held indefinitely for storage and we cannot authorize it for storage indefinitely.

   It is your responsibility to keep the license up to date. Please advise us in a written response what you intend to do to dispose of these sources in a legal manner and when, as in a specific date including a month and year.

   A written response to this item is requested in your next amendment request. Please identify it as "additional information to control number 592420."

3. **Please note that the information you transmitted to us via facsimile on February 17, 2017, did not identify this license at all and was not signed by anyone**

representing Good Samaritan Hospital. Therefore, our information management staff were unable to profile this document correctly and it was attributed/processed into our systems incorrectly, as a direct result of this error. Therefore, we were unable to consider it in the course of this review.

We have included some information below about proper signatories, expedite requests and NRC's regulatory requirements to only provide us with information that is "complete and accurate in all material respects."

Incorporating this information will greatly help to prevent errors, incompleteness and inaccuracies in your 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 <u>not</u> 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 <u>not</u> 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.

Such occurrences should not be routine and address 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.

Signatures Required for Materials Licensing Correspondence and Best Practices

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.

We cannot accept anything that fails to completely identify the licensee it pertains to and that lacks the signature of an appropriate licensee representative, as discussed below and enumerated in our regulations.

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. Please do not ever send us communication documents that fail to completely identify this license, such as with the basic identifying information found on the NRC Form 313, and that have not been signed by an appropriate signatory. We are unable to consider documents lacking this information in the review process.

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 and legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, will 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.""

"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, 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 new license, renewal 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 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.

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.

If you have any questions about this amendment or the information we have requested, please contact me at (630) 829-9841. My fax no. is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

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.

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.

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.

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,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-01787-01
Docket No. 030-01600

Enclosure:

Amendment No. 82