

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 4, 2021

Jennifer Akers, RT(R), MBA Director of Radiology Hannibal Regional Hospital 6000 Hospital Dr. Hannibal, MO 63401

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING HANNIBAL REGIONAL

HOSPITAL AMENDMENT REQUEST AND RENEWAL APPLICATION, NRC

LICENSE NO. 24-18988-01

Dear Ms. Akers:

Our office has reviewed the March 24, 2021 request to amend and the May 21, 2021 application to renew Hannibal Regional Hospital's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 24-18988-01. Upon review, our office has determined that additional information is needed to renew the license, regarding your Radiation Safety Officer (RSO), your Authorized Users (AUs), and your training program for individuals working in or frequenting restricted areas. Your amendment request and renewal application are available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession numbers ML21091A013 and ML21144A073, respectively. The NRC's ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

For additional guidance, please refer to NUREG 1556 Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Sections 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)," pp. 8-16 to 8-21, 8.7.2, "Authorized Users (AUs)," pp. 8-26 to 8-29, and 8.8, "Training for Individuals Working in or Frequenting Restricted Areas," pp. 8-42 to 8-43.

ADDITIONAL INFORMATION REQUESTED REGARDING AUTHORIZED INDIVIDUALS:

- 1. Your amendment request indicated that Timothy R. Keys, M.S., DABR's RSO appointment was limited to 60 days, from April 1, 2021 through May 30, 2021. Your renewal application dated just 9 days prior to the temporary appointment indicated that Mr. Keys is continuing as RSO. Please confirm that Mr. Keys is the permanent RSO, for this license.
- 2. From your amendment request and renewal application, it appears that Mr. Keys may be an external consultant physicist. If Mr. Keys is an external consultant physicist, additional details regarding his availability and alternate licensee contact information may be needed. Please indicate whether Mr. Keys is a full-time employee of Hannibal Regional Hospital, or if he is an external consultant.
- 3. If the RSO is an external consultant, contact information for a routine or full-time employee of the licensee is needed. Please identify at least one in-house representative who will serve as the point of contact during the RSO's absence from the licensee's facility. Please include the in-house individual's name, title, phone number, and email address.

4. The requests did not address the external consultant-RSO's availability, if applicable. Please identify other commitments of the Mr. Keys for other NRC or Agreement State licensed facilities, along with a description of how he will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the Mr. Keys' minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).

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- 5. The requests did not address the external consultant-RSO's availability. Please describe Mr. Keys' availability to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
- 6. The requests did not address the external consultant-RSO's emergency response capability. Accordingly, please specify the maximum amount of time it will take Mr. Keys to arrive at the facility in the event of an emergency that requires his presence.
- 7. The amendment request indicated that the new AU, J. Edward Bass, M.D., has been listed on Amendment No. 42 to Alabama Radioactive Material License No. 555, signed March 26, 2014. Authorizations for the use of unsealed byproduct material for which a written directive is required (equivalent to 10 CFR 35.300) were limited on the reference license to oral administration of sodium iodide I-131 in quantities of 33 millicuries or less. There is no authorization on the referenced license for other uses pursuant to the Alabama Department of Public Health equivalent of 10 CFR 35.300. Additional training and experience documentation would be needed to authorize Dr. Bass for 10 CFR 35.300 uses not authorized on the referenced license. Accordingly, please either: (1) confirm that Dr. Bass' 10 CFR 35.300 materials use authorization should be listed as "limited to the oral administration of sodium iodide I-131 in quantities of 33 millicuries or less or (2) provide documentation of Dr. Bass' supplemental 10 CFR 35.300 qualifications, as described in 10 CFR 35.390 or 10 CFR 35.394.

ADDITIONAL INFORMATION REQUESTED REGARDING TRAINING:

8. The response in the application was not consistent with the current guidance. Please confirm the current guidance statement that, "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

Please provide a response via a signed and dated letter within 28 days (on or prior to July 2, 2021). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

J. Akers 3

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster Date: 2021.06.04 10:26:24 -05'00'

Sara A. Forster, M.S. Health Physicist Materials Licensing Branch Division of Nuclear Materials Safety

Docket No.: 030-17616 License No.: 24-18988-01

Control No.: 625821

From: Forster, Sara

To: <u>Tim Keys</u>; <u>Akers</u>, <u>Jennifer</u>

Subject: Additional Information Request re Hannibal Regional Hospital, Lic. 24-18988-01, CN625821

Date: Friday, June 04, 2021 11:10:00 AM

Attachments: CN625821.Lic24-18988-01 RFAI letter public signed.pdf

Good afternoon, Mr. Keys & Ms. Akers:

Our office has reviewed the March 24, 2021 amendment request and the May 21, 2021 renewal application for the U.S. NRC Radioactive Materials License referenced in the subject line of this message. Upon review, our office has determined that additional information is needed to renew the license, as described in the attached document. For additional guidance, please refer to NUREG 1556 Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Section 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)," pp. 8-16 to 8-21, Section 8.7.2, "Authorized Users (AUs)," pp. 8-26 to 8-29, and Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas," pp. 8-42 to 8-43.

Please provide a response via a signed and dated letter within 28 days (on or prior to July 2, 2021). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

Thank you in advance for your prompt attention to this request,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III Division of Nuclear Materials Safety 2443 Warrenville Rd. - Ste. 210 Lisle, IL 60532-4352

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