

Parker, Bryan

From: Parker, Bryan
Sent: Wednesday, June 24, 2015 3:11 PM
To: 'smshah@evcancntr.net'
Subject: NRC License Renewal - need additional info
Attachments: St Marys Health 585829 RAI.docx

Dr. Shah,

I am performing the review of the renewal of your NRC License No. 13-03226-04 and need some additional information to continue that review.

Please review the attached Request for Additional Info and let me know if you have any questions. You may respond electronically by attaching a **signed PDF file of your response** to an email and sending it to me. Indicate that it is "**Additional Info for CN 585829.**"

I'm hoping this can be turned around quickly so I complete the review soon. Please provide a response within 14 days (by Wed July 8) if at all possible.

Again, if you have any questions, please let me know.

Also, please acknowledge your receipt of this RAI with a quick return e-mail.

Thank you.
Bryan

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Request for Additional Information

St. Mary's Health, Inc. - Evansville, IN (CN 585829)

1. With regard to Item 5 of your application dated 1/22/15, please specify the total possession limit for 10 CFR 35.300 materials. (NOTE: It is currently listed as 5 curies total and includes I-131.)
2. With regard to Item 5 of your application dated 1/22/15, please clarify if PET isotopes are being used. There is an attached diagram in your application dated 1/22/15 that would indicate such use. If this is case, please provide a shielding analysis and calculations for the PET use area to show that dose levels in unrestricted areas are below Part 20 limits for public dose.
3. With regard to Item 7 of your application dated 1/22/15:
 - A. Please provide an updated Delegation of Authority for the RSO.
 - B. The list of authorized users does not include any users for 35.1000 or for 31.11. Please provide an updated list of authorized users. Also, please update training information for the blood irradiator users – **see Condition No. 13 of your current license as a reference.**
4. With regard your application dated 1/22/15, page 15, "*Information Regarding Authorization to I-125 or Pd-103 Seeds for Localization of Non-Palpable Lesions as per 10 CFR 35.1000*," we need additional information:
 - A. Under "AUTHORIZED USER," you request Dr. Charles Lackey to be authorized user and indicate that he is a 35.100/200 user on the license. But you did not include sufficient information regarding his supervised work experience using seeds nor a preceptor attestation from a supervising 35.490 authorized user. Please provide this information. (NOTE: For reference, please see the guidance related to this type of use in the NRC Medical Toolkit - <http://www.nrc.gov/materials/mcu/med-use-toolkit/seed-localization.pdf>.)
 - B. Also under "AUTHORIZED USER," you indicate training for General Surgeons, but you did not fully address training for pathology personnel. Please include a description of that training. (Again, see the aforementioned guidance document.)
 - C. Under "Written Emergency Procedures for Responding to an Abnormal Situation," the emergency procedures submitted are incomplete and/or need clarification. Please review the Safety Precautions and Instructions in the aforementioned guidance document and re-submit these procedures.