NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 04/19/2016

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
James Hatten	04/19/2016	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS: jhatten@sahci.com	TELEPHONE NUMBER: (815) 370-6538	

ORGANIZATION	DOCKET NUMBER(S)
Pinnacle Hospital	030-38910
LICENSE NUMBER(S): Pending	CONTROL NUMBER(S): 590308

SUBJECT

Request for Additional Information

SUMMARY

Based on our review of your application dated February 18, 2016, it appeared that your application had not been completely prepared in accordance with the guidance in NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Licenses."

1. In you application you requested to use 10 CFR 35.300 materials, specifically I-313 in quantities greater than and less than 33 mCi and also to use 10 CFR 31.11. However you did not request any authorized users for 10 CFR 31.11 or 10 CFR 35.300 for I-313 in quantities greater than 33 mCi. Please either provide an Authorized User for these materials or a request to no include the material in the license. Please also confirm in writing if you will be using PET radioncluides. If you will be using PET materials, please provide shielding details for areas where the materials will be used and stored.

2. In your application, you provided a board certification for Dr. Vijay Shah, however you did not provide a preceptor for him or where he is currently listed on another license. Please provide either a preceptor or a license number where he has been listed as an AU.

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ACTION REQUIRED (IF ANY)

Please submit your response by April 29, 2016, and reference it to my attention as "additional information to control number 590308" to facilitate proper handling in our office. Your response must be currently dated and signed . If you have any questions or require clarification of any of the information stated above, please do not hesitate to contact me at 630-829-9607

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NAME OF PERSON DOCUMENTING CONVERSATION

Jennifer L. Bishop

SIGNATURE

Jennifer L. Bishop

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

3. In your application, you did not include information regarding the calibration of your survey instruments. Please response with the following: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." and/or "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."

Please also include a description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

Please also respond with: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

4. In your application, you did not include information regarding the calibration of your dose calibrator. Please respond with the following: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

5. In your application, you did not include information regarding how you will evaluate occupational dose. Please respond with either "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses:." or A description of an alternative method for demonstrating compliance with the referenced regulations.

6. In your application, you did not include information regarding area surveys. Please respond with "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20. 1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

7. In your application, you did not include information regarding the safe use of unsealed materials. Please respond with "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

8. In your application, you did not include information regarding spill/contamination procedures. Please response with "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

9. In your application, you did not include information regarding waste management. Please respond with a statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20. 1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

10. The drawing of you facility was not clear on where licensed materials will be maintained and stored. Specifically, it is not clear where the hot lab will be maintained and where the patient treatment areas will be located. Please provide more clear drawings on where materials will be used and stored.