NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Debbie Lundy	11/18/2019	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS dlundy001@defiance.edu	**TELEPHONE NUMBER** (260) 434-1177	
ORGANIZATION Summit Medical Associates, LLC	**DOCKET NUMBER(S)** 030-38056	
LICENSE NAME AND NUMBER(S) Summit Medical Associates, LLC 13-32752-01	**MAIL CONTROL NUMBER(S)** 613673	

SUBJECT

NRC License Renewal - Additional Information Required

SUMMARY AND ACTION REQUIRED (IF ANY)

This is a summary of the conversation that occurred between Laura Cender and Debbie Lundy on November 18, 2019 regarding the additional licensing information received Nov. 5, 2019.

Per our discussion today, please provide a response to the following items by no later than Dec. 6, 2019:

1. The file received Nov. 5, 2019 was submitted with NRC Form 313 dated Oct. 12, 2019 and with a separate cover letter dated April 29, 2019. The information submitted was requested by the NRC on Nov. 4, 2019. 10 CFR 35.12(a) requires that applications must be signed by licensee management. Please incorporate the following items into your response and resubmit with an appropriate signature and date.

2. Please submit a response to Item 5 and Item 6 of the license application regarding authorized materials and uses to be listed on the license that has been prepared in accordance with Table C-1 of NUREG 1556 Vol. 9 Rev. 3 (see attached).

3. Regarding the submitted facility diagram, please address the following items:
   - Please include the direction North on the facility diagram
   - Please indicate room numbers for the hotlab and surrounding areas. Please indicate if there are no room numbers present.
   - Please indicate if there is a sink present in the hot lab.

NAME OF PERSON DOCUMENTING CONVERSATION

Laura B. Cender

SIGNATURE	DATE OF SIGNATURE
Laura B. Cender	11/18/2019

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
Summit Medical Associates, LLC 13-32752-01	613673

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

4. In your application you state "MPC Physics handle in house leak tests used pursuant to 10 CFR Part 35."

   Please clarify if leak tests will be performed in house, or if a consultant will be performing leak testing for you. If a consultant will be performing leak tests please provide the following response per the guidance in NUREG 1556 Vol. 9 Rev. 3 Table C-2:

   "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

5. In your application you state "the only person to handle the radiation used in the cardiac studies will be the nuclear technologist or a certified nuclear student as per guidelines." This statement appears to omit the radiation safety officer and authorized users from handling licensed material that is present on site. Additionally, please clarify the circumstances under which a student technologist would handle licensed material and guidelines that you reference.

6. In your application you provide a statement requesting to "please disregard the Radiation Protection Program." Please clarify if this is a request to withdraw the document titled "Summit Medical Associates, LLC Radiation Protection Program Nuclear Medicine" Version 9.0 with implementation date of Sept. 17, 2019 from your licensing file.

   Note that the reviewer will review all submitted information, but you will still be able to revise and update the document and procedures as needed without notifying the NRC.

7. In your application you state that "Any nuclear waste is outline in the Radiation Protection Policy." And later in the application you state that "unused radiation is returned to the manufacturer once the dose(s) have decayed to the appropriate level."

   In the Radiation Protection Program provided (Version 9) your procedures allow for multiple methods of disposing of waste material including disposal to the sanitary sewer in accordance with 10 CFR 20.2003 or disposal of material in regular garbage waste after material decays in storage to background levels, or by returning unit doses directly to the pharmacy.

   Please be aware that your statement that the licensed material will be returned to the manufacturer is a commitment that is in conflict with the procedures that have been submitted.

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-Related Information—Withhold Under 10 CFR 2.390" ❑ **Yes** ❑ **No**			
Radionuclide	**Form or Mfr/Mod No.**	**Max Qty**	**Purpose of Use**
❒Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
❒Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
❒Any byproduct material permitted by 10 CFR 35.300 (Note: Check this box if using all radionuclides covered by 10 CFR 35.300; otherwise, check subsequent boxes if limiting use by radionuclide).	Any	_____ millicuries (mCi)	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300. ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient (Note: Check the inpatient box if keeping patients in-house who have not been released pursuant to 10 CFR 35.75. If releasable, check outpatient.)
❒Iodine-131 permitted by 10 CFR 35.300	Any	___mCi	Oral administration of sodium iodide iodine-131. ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient
❒Samarium-153 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of samarium-153 ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient
❒Radium-223 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of radium-223 ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient
❒Lutetium-177 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of lutetium-177 ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient