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	11/04/2019	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS	**TELEPHONE NUMBER**	
dlundy001@defiance.edu	(260) 434-1177	
ORGANIZATION	**DOCKET NUMBER(S)**	
Summit Medical Associates, LLC	030-38056	
LICENSE NAME AND NUMBER(S)	**MAIL CONTROL NUMBER(S)**	
Summit Medical Associates, LLC 13-32752-01	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 4, 2019 regarding the license renewal request received July 24, 2019.

An incomplete license renewal application was submitted. In order to renew your license please submit the following items:

1. Complete the attached NRC Form 313 Items 1, 2, 3, 4, and 13 and submit to the appropriate Regional Office. As noted above, the form must be signed by a duly authorized individual. Please include the individuals title (i.e. president, owner, etc.) when completing the application.

2. Attach Responses to NRC Form 313 Items 5 through 11 to the completed NRC Form 313.

Detailed guidance for completing each application item requested on the NRC Form 313 is located in Chapter 8, "Contents of an Application" in NUREG 1556 Vol. 9, Rev. 3.

For the convenience and streamlined handling of 10 CFR 35.100 and 10 CFR 35.200 applications, licensees may use Tables C.1, "Items 5 and 6 on NRC Form 313: Radioactive Material and Use," and C.2., "Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal," to Appendix C, "License Application Checklists," to the January 2019 guidance to provide supporting information. See attached.

NAME OF PERSON DOCUMENTING CONVERSATION

Laura B. Cender

SIGNATURE	DATE OF SIGNATURE
Laura B. Cender	11/04/2019

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)

3. Please include a copy of your Letter of Understanding (i.e. Delegation of Authority) regarding your responsibilities under 10 CFR 35.24 with this resubmission of your application.

4. A copy of the Summit Medical Associates, LLC Radiation Protection Program was received on Oct. 29, 2019. Per our discussion today, please include your request to withdraw this document with this submission.

Please submit your completed application via fax to 630-515-1078 by no later than Friday, Nov. 15, 2019. Please contact me at 630-829-9712 if you have any questions or if you will be unable to submit your application by this deadline.

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.

NRC FORM 313 (06-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 06/30/2019**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER _____
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

FEE CATEGORY ☐ AMOUNT ENCLOSED $ ☐

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

APPENDIX C

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF U.S. NUCLEAR REGULATORY COMMISSION FORM 313

Suggested Format for Providing Information Requested in Items 5 Through 11 of U.S. Nuclear Regulatory Commission Form 313

This Appendix contains the suggested format that may be used to assist in organizing an application, including the U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License," (Appendix B) and the NRC Form 313A series, "Medical Use Training and Experience and Preceptor Attestation," which can be found on the Medical Uses Licensee Toolkit Web page. Also refer to the NRC Forms Web site at: https://www.nrc.gov/reading-rm/doc-collections/forms/ for the NRC Form 313A series. Verify that the most current version of the NRC Form 313A is being used by checking the "Expires" date in the right, top-hand corner of the form. An applicant may copy the checklist and include it in the license application.

Items 1–4 and 12–13 may be completed on NRC Form 313. Table C–1 provides a suggested format for providing information requested in Item 5 (Radioactive Material) and Item 6 (Purpose of Use), and Table C–2 provides a suggested format for providing information requested in Items 7 and 8 (Training and Experience), Item 9 (Facilities and Equipment), Item 10 (Radiation Safety Program), and Item 11 (Waste Management). Table C–3, Applicable Appendices Describing Model Procedures, may be helpful to applicants in developing procedures for inclusion in their radiation safety program. Please note that the procedures provided are not all-inclusive (e.g., full calibration and emergency procedures for therapy devices are not included and only references to American Association of Physicists in Medicine and American National Standards Institute standards are made in this NUREG document). In addition, uses conducted under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 may require procedures specific to the emerging technology; however, the procedures described in the document may be helpful in developing these procedures. Finally, Appendices X, Y, and Z of this NUREG are not model procedures; however, they are included in Table C–3 to remind licensees of recordkeeping, reporting, and transportation requirements.

The applicant should review the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," and mark security-related sensitive information appropriately.

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

Table C–2 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name of the radiation safety officer (RSO) in Table C–2 and then check the boxes indicating which documents pertaining to the RSO are included in the license application. An applicant may copy the checklist and include it in the license application. Personal information about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of private information are social security number, home address, home telephone number, date of birth, and radiation dose information. If private information is submitted, it should be separated from the public portion of the application and clearly marked: "Privacy Act Information—Withhold Under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," for more information.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal
Item 7: Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) ❒ Name of the proposed RSO (RSO is required for all licenses) ❒ Name(s) of proposed ARSO(s), if desired (A licensee may choose to identify one or more individuals as ARSOs to support the RSO): • for each proposed ARSO, identify the types of use (e.g., 10 CFR 35.200, 10 CFR 35.300) of byproduct material for which the individual may be assigned duties and tasks under the licensee's program in oversight of the radiation protection program: ❒ 10 CFR 35.100 ❒ 10 CFR 35.200 ❒ 10 CFR 35.300 ❒ 10 CFR 35.400 ❒ 10 CFR 35.500 ❒ 10 CFR 35.600 (teletherapy) ❒ 10 CFR 35.600 (HDR) ❒ 10 CFR 35.600 (gamma stereotactic radiosurgery) ❒ 10 CFR 35.1000- (_____)
❒ **Individual currently or was previously identified as an RSO or ARSO on an NRC or Agreement State license or Master Material License permit for the same materials and use** ❒ Provide an NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee on which the individual was named as the RSO or ARSO[1]. **AND** ❒ If applicable, attach documentation of recent, related continuing education and experience as required by 10 CFR 35.59. **OR**
❒ **Individual is a current RSO or ARSO seeking authorization to be recognized as a RSO or ARSO for the additional medical uses** ❒ Attach documentation of completion of the supervised training and experience specified in 10 CFR 35.50(d) for any new materials or new medical uses requested. **AND** ❒ If not qualified under 10 CFR 35.57(a)(1) or board certified by an NRC-recognized board, attach a written attestation as prescribed in 10 CFR 35.50(b)(2), signed by a preceptor RSO or ARSO, that the individual has successfully completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use licensee. Provide documentation of the board certification, if applicable.

[1]Some Agreement States list ARSOs on licenses prior to implementing equivalent Agreement State requirements to 10 CFR 35.50 effective January 14, 2019. Until all the Agreement States implement the rule which went into effect on January 14, 2019, the licensee will have to document that a proposed ARSO listed on an Agreement State license meets the NRC requirements under a different pathway.

AND

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

❒ Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).

AND

❒ Identify an in-house representative who will serve as the point of contact during the RSO's absence.

AND

❒ Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

AND

❒ Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his/her presence.

Item 7: Authorized Users (AUs)

Authorized User(s) Name(s):

❒ Uses requested:

❒ Provide medical, podiatry, or dental license number and issuing entity (e.g., state or territory)

❒ **Individual is currently or was previously listed as an AU on an NRC or Agreement State license or permit for the same type of use(s) requested**

- Provide an NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License permittee of broad scope on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested

AND

❒ If applicable, attach documentation of recent continuing education and experience as required by 10 CFR 35.59.

OR

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 8: Training for Individuals Working In or Frequenting Restricted Areas Provide the following: ❒ A 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."

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 9: Facility Diagram ❒ Provide the following: • Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated. • Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored. • Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET). • Doors should be indicated, and specify which doors are access controlled (i.e., locked). • Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use, High Dose-Rate/Pulsed Dose Rate & Low Dose Rate Remote Afterloaders, Teletherapy, and Gamma stereotactic radiosurgery (GSR). Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used. • For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used. • For teletherapy facilities, applicants should provide the directions of primary beam use and, in the case of an isocentric unit, the plane of beam rotation is identified in the shielding calculations. • For 10 CFR 35.1000 (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the Medical Uses Licensee Toolkit Web page.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 9: Radiation Monitoring Instruments Provide the following: ❒ A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations." **AND/OR** ❒ A statement that: "We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61." **AND** ❒ 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 is attached.
Item 9: Dose Calibrator and Other Dosage Measuring Equipment For the administration of alpha, gamma, and beta emitting unsealed byproduct materials, we are providing the following: ❒ A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions." **AND** ❒ A description of the equipment used to measure the dosages. **AND** ❒ For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.
Item 9: Sealed Sources in Therapy Unit - Calibration and Use ❒ Provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application. ❒ The applicant for a medical use under 35.1000 should provide the procedures required by 10 CFR 35.12(b)(2) that are described in the licensing guidance posted for that 10 CFR35.1000 medical use on NRC's Medical Uses Licensee Toolkit Web page, or explain why the procedure is not provided.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 10: Occupational Dose Provide the following: ❒ A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502." **OR** ❒ A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'" **OR** ❒ A description of an alternative method for demonstrating compliance with the referenced regulations.
Item 10: Spill/Contamination Procedures Provide the following: ❒ A statement that: "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."
Item 10: Emergency Procedures for Therapy Devices Containing Sealed Sources Provide the following: ❒ Attach procedures required by 10 CFR 35.610. **AND** ❒ If appropriate, review 10 CFR 35.1000 medical use licensing guidance on NRC's Medical Uses Licensee Toolkit Web page, and provide safety and emergency procedures requested for the particular 10 CFR 35.1000 medical use.
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources If requesting that the applicant's own employee(s), who are trained by the manufacturer, be authorized to perform the activities noted in section 8.10.7 of this NUREG, provide the following: ❒ Name of the proposed employee(s) and types of activities requested: _____ _____ **AND**

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
❒ Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND** ❒ Copy of the manufacturer's training certification and an outline of the training in procedures to be followed. **AND** ❒ Written commitment from the licensee that the trained employee will follow manufacturer procedures.
Item 10: Material Receipt and Accountability Provide the following: ❒ A statement that: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded licensed material in storage is secured from unauthorized access or removal licensed material not in storage is maintained under constant surveillance and control records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained." **AND** ❒ If applicable, a statement that "We will comply with the National Source Tracking System (NSTS) reporting requirement, as described in 10 CFR 20.2207."
Item 10: Leak Tests Provide the following: *For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:* ❒ A statement that: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67." **OR** *For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources)*: ❒ A statement that: "We will conduct leak tests in-house." **AND** ❒ A statement that: "The attached leak test procedures will be followed for leak tests conducted in-house." **AND** ❒ Attach leak test procedures.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
OR ❒ A statement that the applicant will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use. For instance, if an applicant possesses a self-shielded irradiator, the applicant may state, "We will implement the model leak test program published in Appendix N of NUREG–1556, Volume 5, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses." **OR** ❒ If a contractor is used to perform leak testing, a statement that: "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."
Item 10: Area Surveys Provide the following: ❒ A statement that: "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."
Item 10: Safe Use of Unsealed Licensed Material Provide the following: ❒ A statement that: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201." **Item 10: Mobile medical service** ❒ Review the guidance in Appendix V of this NUREG to determine the response required.
Item 10: Minimization of Contamination A response is not required under the following condition: The NRC will consider that the criteria have been met if the information provided in the applicant's responses satisfies the criteria for the following sections in this NUREG: Sections 8.9, 8.9.1, 8.10, 8.10.5, 8.10.12, and 8.11 on the following topics: facilities and equipment, facility diagram, radiation safety program, spill and contamination procedures, area surveys, and waste management.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 11: Waste Management Provide the following: ❒ 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." **AND** ❒ Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration or compaction.

Cender, Laura

From: Cender, Laura
Sent: Monday, November 04, 2019 10:23 AM
To: dlundy001@defiance.edu
Subject: NRC Materials License No. 13-32752-01 - Additional Information Required
Attachments: Conversation Record to SMA 11.04.2019.pdf; NRC 313.pdf; NUREG 1556 Vol 9 Rev. 3 Appendix C.pdf

Hello Debbie,

Thank you for taking time out of your morning to discuss your pending NRC license renewal request, a record of our conversation is attached. As the original license renewal application received July 24, 2019 was incomplete, we request that the application be resubmitted in entirety.

Attached are copies of NRC Form 313 and an accompanying checklist that describes the information required for license renewal. Section 8 of NRC guidance document NUREG 1556 Vol. 9 Rev. 3 "Consolidated Guidance About Materials Licenses" provides detailed guidance on completing each step of the application. The full guidance document can be accessed at the following link: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf.

Please submit your completed and appropriately *signed and dated* application by no later than *Friday, November 15, 2019*. For ease of processing please submit your application via fax to our regional office at (630) 515-1078. You may also mail your application directly to our regional office at the address below.

U.S. Nuclear Regulatory Commission
Materials Licensing Branch
2433 Warrenville Road
Suite 210
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Thank you,
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