APPENDIX C

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

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued)
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
❒Other byproduct material permitted by 10 CFR 35.300 _____ (please specify)	Any	___mCi	❒inpatient (facility diagram of patient room(s) attached) ❒outpatient
❒Iodine-125 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No._____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400.
☑Palladium-103 permitted by 10 CFR 35.400	Sealed sources (Manufacturer Theragenics - Theraseed _____, Model No. _____)	___mCi 4 mCi / source 4 Ci total	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ✓
❒Iridium-192 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒inpatient (facility diagram of patient room(s) attached)
☑Cesium-131 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi 10 mCi / source 1 Ci total	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ✓
❒Cesium-137 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒inpatient (facility diagram of patient room(s) attached)
❒Strontium-90 permitted by 10 CFR 35.400	Sealed source (Manufacturer _____, Model No._____)	___mCi	Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
❒ Other byproduct material permitted by 10 CFR 35.400 _____ (please specify)	Sealed source (Manufacturer _____, Model No. _____)	____mCi	_____(specify authorized use) ❒inpatient (facility diagram of patient room(s) attached) ❒outpatient

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) Stephen M. Kurtzman, MD
DoA provided

☐ Name(s) of proposed ARSO(s), if desired (A licensee may choose to identify one or more individuals as ARSOs to support the RSO): Ankit Agarwal, MD - ARSO

- 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** Both listed as RSO/ARSO respectively on CA License No. 8101-01

☑ Provide an NRC License # CA 8101-01 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. NA - issued Oct. 2023

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.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
❑ **Individual is applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50(c)(3)** ❒ Attach the license application that includes documentation of the training and experience of the new AU **AND** ❒ Attach documentation of supervised training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO **OR**
❒ **Individual is qualifying by classroom/laboratory training and supervised radiation safety experience under 10 CFR 35.50(b)**: ❒ Attach documentation of the training and experience specified in 10 CFR 35.50(b)(1) in completed NRC Form 313A (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training and experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO. **AND** ❒ Attach documentation of supervised training and experience specified in 10 CFR 35.50(d) in attached NRC Form 313A (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO. **AND** ❒ Attach a written attestation, as prescribed in 10 CFR 35.50(b)(2), signed by a preceptor RSO or ARSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b)(1), as well as the required training 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 ARSO for a medical use license. **AND** ❒ If applicable, attach documentation of recent related continuing education and experience as required by 10 CFR 35.59. **AND**
☑ **For a proposed RSO who is an outside consultant or contractor, address the following**: ☑ An outside consultant or contractor must qualify as an RSO in accordance with 10 CFR 35.50 or 10 CFR 35.57 and 10 CFR 35.59 criteria specified above.

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: Ankit Agarwal MD, Stephen Kurtzman M.D.

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

☑ **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 #CA 8101-01 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.
Current AUs as of Oct. 2023

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.	NA
• 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.	

All patients will be releasable per 35.75

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 NA - seeds only

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 NA - 35.400 seeds only.

☐ 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 9: Other Equipment and Facilities

Provide the following, if applicable:

- ❒ For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable.
- ☑ For manual brachytherapy facilities, provide a description of the emergency response equipment.
- ❒ For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:
  - ❒ Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
  - ❒ Area radiation monitoring equipment
  - ❒ Viewing and intercom systems (except for low dose-rate units)
  - ❒ Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
  - ❒ Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons
  - ❒ Emergency response equipment
- ❒ For 10 CFR 35.1000 medical uses, review the licensing guidance posted for that 10 CFR 35.1000 medical use on NRC's Medical Uses Licensee Toolkit Web page and provide the appropriate descriptions of other equipment and facilities.

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 NA

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 NA

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 NA

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." NA

Item 10: Leak Tests Ok - exempt under 35.67(f)(1)

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 NA - sealed materials only 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** NA ❒ Review the guidance in Appendix V of this NUREG to determine the response required.
Item 10: Minimization of Contamination NA 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.

Ok - licensee has committed to returning leftover seeds to vendor immediately following procedures.