

From: [Winslow, Mark](#)
To: [Simmons, Michelle](#)
Cc: [Joseph Skovron](#); [Albertson, Landon J](#)
Subject: [External_Sender] RE: [EXTERNAL] RE: RE: Checklist/PIC
Date: Thursday, March 19, 2020 6:58:13 PM
Attachments: [PIC NRC Letter 61682.pdf](#)

Please find the formal cover letter attached. I apologize for the line going through the scan, I am working from home.

From: Simmons, Michelle [mailto:Michelle.Simmons@nrc.gov]
Sent: Thursday, March 19, 2020 10:07 AM
To: Winslow, Mark <Mark.Winslow@providence.org>
Subject: [EXTERNAL] RE: RE: Checklist/PIC

Yes, that's it.

Thank you.

From: Winslow, Mark <Mark.Winslow@providence.org>
Sent: Thursday, March 19, 2020 11:50 AM
To: Simmons, Michelle <Michelle.Simmons@nrc.gov>
Cc: Joseph Skovron <joe@nwradservices.com>
Subject: [External_Sender] RE: Checklist/PIC

Is this what you are looking for? I put down a check for items that were applicable and NA for items that do not apply. If this is what you need I will move forward with the formal letter.

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PROVIDENCE IMAGING CENTER

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March 19, 2020

Nuclear Regulatory Commission
Materials Licensing and Decommissioning Branch
Region IV
1600 E Lamar Blvd
Arlington, TX 76011-4511

RE: Mail Control Number 61682
Renewal of Providence Imaging Center license – 50-29357-01

Dear Ms. Simmons:

In response to your email dated 3/19/2020, you requested we complete the checklist from NUREG 1556 Volume 9, Rev 3. Please find the checklist attached.

We have reviewed the checklist and checked items that are applicable to our license application. We have confirmed these items or equivalents are in place.

Sincerely,

Mark P. Winslow, Ph.D., DABR
Sr. Chief Medical Physicist
Radiation Safety Officer

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 CFR 35.1000 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. *N/A*

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. *N/A*

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. *N/A*

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: *N/A*

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." *N/A*

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 *N/A*

- ☐ 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.