UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

MAR 06 2018

Arthur J. Frazier, M.D.
Radiation Safety Officer
Mount Clemens Regional Medical Center
d/b/a McLaren Macomb
1000 Harrington Blvd.
Mount Clemens, MI 48043

Dear Dr. Frazier:

We have reviewed your letter dated January 5, 2017, received in our offices on January 23, 2018, requesting new authorization for yttrium-90 SIRSpheres permitted by 10 CFR 35.1000, and find that we will need additional information to complete our review.

Please prepare a written response that completely and concisely covers all of the items below, as appropriate, and submit it within 15 days of the date of this letter, by March 20, 2018, or contact me to make alternative response time arrangements. Please mark your written response to my attention at the address shown at the top of this letter and reference it as "additional information to control number 602232."

If you have any questions or comments concerning this amendment, please contact me at (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov but please do not transmit your response via email or PDF. Faxing it directly to the number above is quickest.

We are sending this letter in regular mail to you, Dr. Frazier, and we are contacting your designated point of contact for the Y-90 SIRSpheres program request, Trevor London, at 586-493-8070 and Trevor.london@mclaren.org to determine how best to convey this letter to him.

Please provide only one complete, written response that is currently dated and signed by a senior management official for this license. This will help ensure that your response is processed correctly in our offices.

A. In addition to the items below, please also see the enclosed "marked up" pages from the Licensing Guidance for Y-90 SIRSpheres in 10 CFR 35.1000, from our website. I have marked the sections that we need you to explicitly commit to, in the same level of detail as shown.

   Please respond by making each requested commitment in the same level of detail as shown in the Guidance.

Please do not make "blanket" or "partial blanket" statements, such as "We commit to xxxxxxxxxxxxxx in accordance with NRC's February 2016 Licensing Guidance." This type of statement does not constitute actual, detailed commitments, statements and representations. If such statements were "approvable," our Licensing Guidance would state as much and it does not.

Please do not resubmit any information you have already sent us in the January 5, 2017 letter that we have not asked for as additional information now. To do so will likely delay the review of your written response.

We have not considered in our review the following documents, that you submitted with the letter dated January 5, 2017, and that we did not ask for in our Licensing Guidance:

- The SIR-Spheres Authorized User Checklist; and,
- The SIR-Spheres Y-90 Preparation and Verification Procedure.

Please do not resubmit these, or other, similar, documents. Please also note that such documents do not constitute the actual, explicit, specific commitments, statements and representations that are requested in our Licensing Guidance.

B. In Item 5 of your letter dated January 5, 2017, you made several statements requesting "exemption from the semi-annual inventory in the NRC microsphere guidance rev.9 dated February 2016, and instead commit to the requirements as outlined in the new NRC microsphere guidance revision 10 draft dated October 2017."

Please note that your request is unacceptable and cannot be considered, in part because the Revision 10 Draft Guidance dated October 2017 is marked "Draft for Comment Only." The Draft Guidance is not available for actual use yet as it is not in "Final" form.

Further, it is inappropriate to request an "exemption" from NRC guidance. "Exemption" is an appropriate term to use regarding relief from a regulation only and the inventory requirements for Y-90 SIR-Spheres are contained in Guidance, not a regulation.

NRC's regulations in 10 CFR 30.11 and Section 4.13 and Appendix K in NUREG 1556 Vol. 20, "Consolidated Guidance About Materials Licenses, Guidance About Administrative Licensing Procedures," dated December 2000, may be helpful to you in understanding NRC's use and application of this term.

If or when you respond to this request for additional information and if we are eventually able to approve the Y-90 SIRSpheres modality in 10 CFR 35.1000 for your license, we will be excluding all of the information in Item 5 from your letter dated January 5, 2017.

Please note that we have included a request for your commitment to the inventory elements in the Guidance document dated February 12, 2016, in the attached "marked up" excerpts from the Guidance.

C. In the current version of the Y-90 Microspheres brachytherapy guidance there is a statement under "Licensing Guidance": "Applicants are reminded that licenses issued

pursuant to 10 CFR 35.1000 must still meet the general requirements in Part 35, Subparts A, B, C, L, and M, except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Part 30."

The need for all human use licensees to have an RSO is in 10 CFR 35.24, of course, and the RSO qualification requirements are in 10 CFR 35.50, both of which are in Subpart B.

1. In order for us to approve the new 10 CFR 35.1000 modality, limited to Y-90 SIRspheres, your current Radiation Safety Officer (RSO) and senior management must submit a new Delegation of Authority (DoA) expanding the RSO's duties and responsibilities to the new modality and stipulating that he accepts these duties and responsibilities.

   A sample of a DoA that you can use as a template for this purpose can be found on the last page of Appendix I in NUREG 1556 Vol. 9, Rev. 2. This document is on our website at: https://www.nrc.gov/docs/ML0734/ML073400289.pdf and we have attached an excerpt from Appendix I to this letter.

2. Your RSO must also have training in the radiation safety, regulatory issues and emergency procedures for the Y-90 SIRspheres program, in accordance with 10 CFR 35.50 (d) and 35.50 (e).

   Please submit a preceptor attestation, appropriately signed by another medical use RSO, who is already qualified for the use of Y-90 SIRSpheres, and currently dated, to support the 10 CFR 35.1000 modality, limited to Y-90 SIRspheres, for your current Radiation Safety Officer (RSO).

   Please note that we are not re-qualifying Dr. Frazier for everything on the license again, only the additional, new Y-90 SIRspheres modality in 10 CFR 35.1000.

   "Marked up" excerpt copies of 10 CFR 35.50; and excerpts from Appendix B and Appendix D in NUREG 1556 Vol. 9, Rev. 2 are also attached and should be useful to you in preparing your response.

D. The following is some general information, compiled from deficiency correspondence I've prepared over the years, to assist you in preparing not only this response, but also any future licensing actions, to minimize or eliminate requests we must make for additional information. This can greatly lessen the workload for you and for us and permit us to serve you better. No specific response is required or requested but maintaining awareness of this information should prove very useful to you in preparing future licensing correspondence.

   Please be reminded that USNRC is an independent and objective federal government regulator.

   This is not intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

In preparing your response, please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

What this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved.

Only after the request has been thoroughly vetted and corrected by the applicant/licensee should the licensing correspondence be transmitted to NRC.

This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

E. For Y-90 Microsphere Brachytherapy licensing specifically:

Please refrain from submitting copies of "off the shelf" licensing packages prepared by other licensees, vendors or consultants. We understand that these packages may seem to be convenient but Y-90 Microsphere Brachytherapy licensing authorizations are not "one size fits all," even for the same vendor/supplier, considering that 37 Agreement States each have their own requirements and guidance, in addition to that of the NRC.

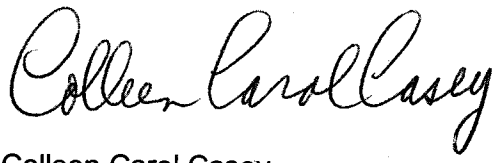
Experience has shown that these documents are not crafted to address current NRC regulations and guidance very well.

Using such documents may "over-commit" your Y-90 Microsphere Brachytherapy licensing program in several areas and "under-commit" your program in most others. This creates the need to contact you for additional information resulting in mutual delays and extra work.

In addition, please do not send us extraneous documents beyond what is needed to support your application, such as vendor's operations manuals, vendor's emergency procedures manuals, Authorized User checklists, lengthy procedure details, patient instructions and explanations, patient records, resumes, college transcripts, and any personally identifiable information.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-04080-01
Docket No. 030-02040
Control No. 602232

Enclosure: As stated

Cc w/enclosure:

Trevor London, CNMT
Supervisor, Nuclear Medicine
McLaren Macomb Hospital
Attn: Diagnostic Imaging/Trevor London
1000 Harrington
Mount Clemens, MI 48043

10 CFR 35.1000 Use

Although yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy, Y-90 microspheres have many unique properties that merit radiation safety considerations other than those required by 10 CFR Part 35, Subpart F, "Manual Brachytherapy." These unique properties include their small size; the large number of microspheres used in a treatment; the route of administration; and their use by physician authorized users (AU) in addition to radiation oncologists, including nuclear medicine physicians and interventional radiologists. As a result, Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of TheraSphere® and SIR-Spheres® and is not intended to be the only means of satisfying the requirements for a license. The applicant must submit the information required by 10 CFR 30.33 and 35.12, as described below. The applicant should submit additional information and commitments requested below or may, unless the information is specifically required by regulation, submit alternative information and commitments for review by the U.S. Nuclear Regulatory Commission (NRC) staff to make a licensing determination. The commitments incorporated into the applicant's license by license condition will be reviewed during routine inspections. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in Part 35, Subparts A, B, C, L, and M, except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Part 30.

License Commitments

The applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

Training

The applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Procedures for Administration

The licensee shall commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods.

Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

Written Directives

For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity should be used for all documentation and evaluations.

The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

Termination of Treatment Due to Stasis

If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Emergent Patient Conditions

If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Medical Event Reporting

The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

- the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
- the administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or

- the total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or
- the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Inventory

The semi-annual physical inventory of microsphere aggregates (e.g., vials) should include:

- the radionuclide and physical form; and
- unique identification of each vial in which the microspheres are contained; and
- the total activity contained in each of the vial(s); and
- the location(s) of the vial(s).

The licensee shall retain each semi-annual physical inventory record for three years.

Labeling

The licensee should commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Patient Release

The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

Radiation Protection Program Changes

This guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

An applicant initially applying for authorization for the medical use of TheraSphere® and SIR-Sphere® Y-90 microspheres, or a licensee applying for an amendment to conform with this revision of the guidance may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1. the revision is in compliance with the regulations; and
2. the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Medical Uses Licensee Toolkit;
3. the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
4. the affected individuals are instructed on the revised program before the change is implemented; and
5. the licensee will retain a record of each change for five years; and

6. the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

Notes to Licensees

Change in Physical Conditions of Use

If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of Other Y-90 Microspheres

The SSD safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 microspheres, including the preparation of Y-90 on or in other microspheres by a commercial nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSD safety evaluation for a given manufacturer's Y-90 microsphere delivery system does not cover the use of that manufacturer's Y-90 microspheres with another manufacturer's delivery system or the use of another manufacturer's Y-90 microspheres with the given manufacturer's delivery system. Before authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres.

U.S.NRC
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Protecting People and the Environment

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics-

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; or

(2) [Reserved]

(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities and,

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

[70 FR 16361, Mar. 30, 2005; 71 FR 1926, Jan. 12, 2006; 71 FR 15008, Mar. 27, 2006; 74 FR 33904, Jul. 14, 2009; 76 FR 72085, Nov. 22, 2011]

Page Last Reviewed/Updated Tuesday, August 29, 2017

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

UPDATE + REVISE TO INCLUDE 35.1000 Y-90 SIR-SPHERES

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____

Signature of Management Representative Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Affected department heads

Part II. Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. The preceptor language in NRC Forms 313A (AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual has the knowledge to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and a completed preceptor attestation). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in 3.c) and a completed preceptor attestation in Part II). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO. This is documented in Section 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

NRC FORM 313A (RSO) (2-2007) | U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Radiation Safety Officer

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400 ☐ 35.500 ☐ 35.600 (remote afterloader)

☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the four methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

OR

☐ **2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above**

a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.

b. Skip to and complete Part II Preceptor Attestation.

OR

☐ **3. Structured Educational Program for Proposed Radiation Safety Officer**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			
Total Hours of Training:			

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Structured Educational Program for Proposed Radiation Safety Officer (continued)**

b. Supervised Radiation Safety Experience
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ _____ _____ _____ _____		

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer

This license authorizes the following medical uses:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400

☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)

☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual

License/Permit lists supervising individual as:

☐ Radiation Safety Officer ☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400

☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)

☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

OR

☐ **4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license**

a. Provide license number.

b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

☐ **1. Board Certification**

☐ I attest that _____ (Name of Proposed Radiation Safety Officer) has satisfactorily completed the requirements in 10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☐ **2. Structured Educational Program for Proposed Radiation Safety Officers**

☐ I attest that _____ (Name of Proposed Radiation Safety Officer) has satisfactorily completed a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)
Check one of the following:

☐ 3. **Additional Authorization as Radiation Safety Officer**

☐ I attest that _____ is an
Name of Proposed Radiation Safety Officer

☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section
Complete for all *(check all that apply)*:

☐ I attest that _____ has training in the radiation safety, regulatory issues, and
Name of ProposedRadiation Safety Officer

emergency procedures for the following types of use:

☐ 35.100

☐ 35.200

☐ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

☐ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

☐ 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 parenteral administration of any other radionuclide for which a written directive is required

☐ 35.400

☐ 35.500

☐ 35.600 remote afterloader units

☐ 35.600 teletherapy units

☐ 35.600 gamma stereotactic radiosurgery units

☐ 35.1000 emerging technologies, including:

_____

_____

_____

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

Third Section
Complete for ALL

☐ I attest that _____ has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer

sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for _____
Name of Facility

License/Permit Number: _____

Name of Preceptor	Signature	Telephone Number	Date

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