From: Tripp, Lester
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Subject: Request for Additional Information in Support for New License Issuance
Date: Wednesday, March 19, 2014 3:05:00 PM
Attachments: NRC 313A(AUS).pdf

Docket No. 03038713
License No. 52-35129-01
Control No. 583121

Michael Ocasio, M.S.
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Bayamón, PR 00960

Date: 03/19/2014

SUBJECT: PRECISE RADIATION ONCOLOGY CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 583121

Dear Mr. Ocasio:

This correspondence is in reference to your application dated February 6, 2014 applying for a Nuclear Regulatory Commission license. There are sections of your application that follow NRC Regulatory Guide 10.8, Revision 2, "Guide for Preparation of Applications for Medical Use Programs," and refer to Model Procedures published in this guide. Please note that this guide was published in August 1987 and was designed for use with the NRC's medical regulations that existed in 10 CFR Part 35 at that time. On April 24, 2002, NRC published new medical regulations in 10 CFR Part 35. These regulations became effective on October 24, 2002. Concurrent with the issuance of the new medical regulations, NRC published NUREG 1556, Volume 9, "*Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.*" (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/,*).* As specified in NUREG-1556, Volume 9, Revision 2, Regulatory Guide 10.8 is superceded and should no longer be used.

Please use NUREG-1556, Volume 9, Revision 2, in preparing your responses to this letter. In addition, you will note that the current Part 35 and the NUREG generally do not require the submission of detailed procedures during the licensing process. As described in the NUREG, in many cases a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures. Appendix C of NUREG-1556, Volume 9, Revision 2 should be helpful in identifying the information required by NRC to process your request for a license. In order to continue our review, we need the following additional information:

1. In accordance with the guidance provided in NUREG-1556, Vol. 9, Revision 2, please confirm that you request to add the following commitments found in Table C.3 of the NUREG to develop, document, and maintain written procedures that replace Regulatory Guide 10.8 superceded procedures:

   a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations, or that we will develop, implement, and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61". If you will be performing your own calibrations, please identify the source that you will use by source manufacturer and model number, nuclide, activity, and calibration accuracy;

   b. That we reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used;

   c. That the equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions;

   d. For radium-223, unit doses only will be used, or if you plan to use other than unit doses, please provide the following statement: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation";

   d. In reference to occupational dose, that you will "Either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, radiation dose on excess of 10% of the allowable limits in 10 CFR Part 20 or will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Volume 9, Revision 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensee.';

   e. In reference to area surveys, that you 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.";

   f. That you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301;

   g. That you will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR Part 20.1101;

   h. In reference to your waste management procedures, that you have "developed and will implement and maintain written waste disposal procedures for licensed material, in accordance with 10 CFR 20.1101, that also meets the requirements of

the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92."

2. Our records indicate that the proposed authorized user (AU) name has been specified as Lawrence J. Sheplan on another license. You have requested that the name of the authorized user be specified as Lawrence J. Sheplan Olsen. Please confirm that this is the same individual, and how his name should appear on the license.

3. You are requesting that Lawrence J. Sheplan Olsen, M.D., be the authorized user for licensed material permitted by 10 CFR 35.300, and 10 CFR 35.400. *NRC Form 313A (AUT)* dated October 11, 2013 was completed for the use permitted by 10 CFR 35.300 but not signed by the preceptor. Please have the document signed by Dr. Rahul Tedulkar. In order to be authorized for use of licensed material permitted by 10 CFR 35.400, please complete *NRC Form 313A (AUS)* (attached). Please note that Part 1 of this form allows you to use the Board Certification Pathway which allows you to go directly to Part ll Preceptor Attestation.

4. Your license will be written in a format which requires modification of some possession limits and forms. In your response to this letter, please provide limits commensurate with your program and sealed source identification in the format shown below. For sealed sources, please list all manufacturers and model numbers that you currently possess or may use in the future. When setting the limits for the materials below, please consider the maximum activity you will have on site at any one time including waste.

Materials permitted by:	Form or Manufacturer/Model No.	Possession limit:
Strontium 89	Any	___ millicuries
Samarium 153	Any	___millicuries
Radium 223	Any	____millicuries
Iodine 125	Sealed Sources (Manufacturer _____, Model No. _____) (Manufacturer _____, Model No. _____)	 ___ millicuries ___ millicuries

5. Your application requests that Joanna Berrios be named on your license as an alternate Radiation Safety Officer (RSO). The NRC does not recognize alternate or assistant RSOs. The individual listed on an NRC license as the RSO is the individual responsible for overseeing the radiation safety program. However, the RSO may delegate certain tasks to other qualified individuals. The RSO must confirm that those delegated tasks were performed as required and in compliance with NRC regulations and your NRC license

6. On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-c) and describe the type, dimensions, and thickness of shielding that you

will use. Exhibit 6 of the enclosed regulatory guide may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

a. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

b. Storage of brachytherapy sources.

c. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

In addition, identify adjacent areas across the walls from use and storage locations of radioactive materials and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301 (enclosed).

7. Please provide a description of the radiation monitoring instruments that will be used to perform radiation level detection, measurement, and contamination surveys.

8. Information currently available to the NRC indicates that iodine-125 and Pd-103 seeds may become dislodged during implantation or after surgery. Please specify the survey instrument used to locate seeds. This instrument should be equipped with a thin sodium iodide crystal detector probe in order to detect iodine-125. (A sodium iodide (NaI) probe is the most appropriate instrumentation because both I-125 and Pd-103 are very low energy gamma emitters and thus are very difficult to detect using a conventional survey instrument).

9. Describe the emergency response equipment available for your manual brachytherapy facilities.

10. Please confirm that patients administered radioactive materials permitted by 10 CFR 35.300 and 10 CFR 35.400 will be releasable pursuant to 10 CFR 35.75. Otherwise, describe the rooms you will use to house non-releasable patients. Confirm that the patients will be housed in private rooms with private bathrooms. Provide room diagrams including adjacent areas on the same floor, above, and below. Also provide a description of any shielding and show that adequate steps have been taken to ensure that radiation levels will not result in doses to individuals in excess of those specified in 10 CFR 20.1301.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 583121. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5358.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

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