



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

November 1, 2006

Docket No. 03037158
Control No. 139427

License No. 52-31137-01

Tomas Irizarry, M.D.
Western Radiosonics
Calle de Diego #101
Este, Esquina Iglesia
Mayaguez, PR 00680

SUBJECT: WESTERN RADIOSONICS, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 139427

Dear Dr. Irizarry:

This is in reference to your letter dated September 19, 2006 requesting to amend Nuclear Regulatory Commission License No. 52-31137-01. In order to continue our review, we need the following additional information:

1. In your letter dated September 19, 2006, you requested the use of 35.200 and 35.300 materials for uptake, dilution, and excretion studies. These uses are not authorized by 10 CFR 35. 35.200 materials are approved for imaging and localization studies and 35.300 materials are approved for radiopharmaceutical therapy procedures. Please provide the following:
 - a. the uses of 35.200 materials, and
 - b. specify what radiopharmaceutical therapy procedures you wish to perform (oral administration of less than or equal to 33 millicuries of sodium iodide I-131; oral administration of greater than 33 millicuries of sodium iodide I-131; parenteral administration of any beta emitter or photon-emitting radionuclide with a photon energy less than 150 keV; and/or parenteral administration of any other radionuclide).
2. Currently David Rhoe is listed on your possession only license as the Radiation Safety Officer. With the addition of 35.100; 35.200; and 35.300 uses to your license Mr. Rhoe may need to allocate additional time to your facility.
 - a. Therefore, identify Mr. Rhoe's other commitments to NRC or Agreement State licensed facilities, along with a description of how Mr. Rhoe will allocate time to permit the performance of the duties of the RSO as described in the regulations. State Mr. Rhoe's minimum amount of on-site time (hours per week).
 - b. Also, describe the overall availability of Mr. Rhoe to respond to questions or operational issues that arise during the conduct of your radiation safety program

and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

3. 10 CFR 35.59 states, in part, that the proposed authorized user's training and experience must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. A search of our database revealed that you were listed on NRC License No. 52-19984-01 for 10 CFR 35.100, 35.200 and 35.300 uses through October 1992. I was not able to verify additional information on your work experience from 1992 to the present. In your letter dated July 17, 2006 you provided documentation of your recent continuing medical education, however, you did not provide documentation of your recent work experience. Therefore, please provide the following:
 - a. documentation of your work experience within the previous seven years, for example,
 1. a copy of an NRC or Agreement State license listing you as an authorized user, or
 2. a letter, signed by an authorized user listed on an NRC or Agreement State license, attesting to the training and experience you have received during the previous seven years.
 - b. evidence that you have performed a minimum of 3 preceptored cases for each of the following categories for which you wish to be authorized:
 1. Oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required;
 2. Oral administration of greater than 33 millicuries of sodium iodide I-131;
 3. 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; and/or
 4. Parenteral administration of any other radionuclide, for which a written directive is required.
4. In your application, you stated that you would possess a Geiger-Mueller detector for your required radiation level surveys. Please provide a description of the radiation monitoring instrument that will be used to perform surveys for iodine-131 contamination.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government

T. Irizarry
Western Radiosonics

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Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 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. 139427. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

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.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
David Rhoe, Radiation Safety Officer

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SUNSI Review Complete: TWeidner

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