

From: Tara Weidner
To: Pearl@DIGIRAD.com
Date: Wed, Nov 9, 2005 12:08 PM
Subject: SUBJECT: DIGIRAD IMAGING SOLUTIONS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 137245

Dear Mr. Early:

This is in reference to your application dated June 29, 2005 requesting to renew Nuclear Regulatory Commission License No. 31-30666-01. In order to continue our review, we need the following additional information:

1. Please address the following concerning your Base Locations;
 - a. Provide a detailed facility diagram for each base location, indicate the position of each of the areas described below and describe the type, dimensions, and thickness of shielding that you will use. Section 8.15 of NUREG-1556, Vol. 9, Rev. 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated May 2005 may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

1. Receipt and storage of radiopharmaceuticals (refrigerated and nonrefrigerated).
 2. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe how you will secure the material.
 3. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.), if applicable.

In addition, identify adjacent areas across the walls from use and storage locations 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.

- b. Describe the scope of activities that will be performed at each base location that is listed in your application (i.e. base hot lab, patient imaging, etc.) In addition, please specify whether each base location is a commercial (non-medical) or medical facility.

- c. Confirm that Digirad Imaging Services, Inc. owns or leases all base locations listed in your application.

2. With regard to the list of authorized users presented in your application dated June 29, 2005;

- a. Confirm the spelling of Edwin P. Hutsai, M.D. Specifically, the license states that it is Edwin P Hutsal, M.D.

- b. Confirm whether or not Steven Craig Vranian, M.D. is the same person as S. Craig Vranian, M.D.

3. In your application dated June 29, 2005, you stated that, "All contaminated material associated with patient injections, and unused dosages will be returned to the base location (permanent job-site) and will be treated as radioactive and held for decay until background." Please confirm that all licensed material, including unused dosages that are not able to be returned to the radiopharmacy, will be returned to the base location on a daily basis. No licensed material may be stored at the client site overnight.

4. Based on our streamlined approach to licensing defined in NUREG 1556, Vol. 9, Rev. 1 we no longer require specific written procedures to be submitted during the licensing process. These procedures are required to be developed, implemented and maintained by the licensee and will be reviewed during routine inspections. Therefore, regarding your licensed procedures, please provide the following statements, as applicable:

a. Please confirm that you will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated May 2005. Otherwise, describe an alternative method for demonstrating compliance with the referenced regulations.

b. Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

c. We have developed and will 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.

d. We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 Part 20.1101.

e. 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.

f. 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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

5. If you wish to have the ability to upgrade your survey instruments, without amending your license, please provide the following statement in your response, "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."

6. Please confirm that the transportation of licensed materials will be in accordance with 10 CFR Part 71 and Department of Transportation regulations.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select Nuclear Materials; Medical, industrial, and academic uses of nuclear material; then toolkit index page. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 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. 137245. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Tara L. Weidner
Health Physicist

Medical Branch
Division of Nuclear Materials Safety

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From: Tara Weidner

Created By: TLW@nrc.gov

Recipients

DIGIRAD.com

Pearl (Pearl@DIGIRAD.com)

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DIGIRAD.com

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Options

Expiration Date:

None

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