

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 4, 2006

License No.

06-31186-01

Docket No. 03037336

Control No. 139360

John Pizzonia, M.D.

Director

Fuji Medical Systems USA, Inc 300 George Street Suite 5D New Haven, CT 06511

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SUBJECT: FUJI MEDICAL SYSTEMS USA, INC, REQUEST FOR ADDITIONAL

INFORMATION CONCERNING APPLICATION FOR NEW LICENSE.

CONTROL NO. 139360

Dear Dr. Pizzonia:

This is in reference to your application dated September 1, 2006 applying for a Nuclear Regulatory Commission license. In order to facilitate the application process the NUREG-1556 Volume 7 was developed to provide guidance to the applicant in preparing an Academic, Research and Development and Other Licenses of Limited Scope application. A current copy of the NUREG-1556 Volume 7 can be found on the NRC's website at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/.

In order to continue our review, please provide the information requested under "Response from Applicant" found in the NUREG-1556, Vol. 7 with regard to the following sections:

- 1. Section 8.5 Item 5: Radioactive Material
 - a. 8.5.1 Unsealed materials
- 2. Section 8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience
 - a. 8.7.1 Radiation Safety Officer (RSO)
 - b. 8.7.2 Authorized User
- 3. Section 8.10 Item 10: Radiation Safety Program
 - a. 8.10.2 Radiation monitoring Instruments
 - b. 8.10.3 Material Receipt and Accountability
 - c. 8.10.4 Occupational Dose
 - d. 8.10.6 Safe Use of Radionuclides and Emergency Procedures
 - e. 8.10.7 Surveys
- 4. Section 8.11 Item 11: Waste Management

J. Pizzonia Fuji Medical Systems USA, Inc

5. Include the revised diagram of the facility where the radioactive material will be used and stored.

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 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 Lizette Roldán at the Region I Office and refer to Mail Control No. 139360. If you have any technical questions regarding this deficiency letter, please call Lizette Roldán at (610) 337-5399.

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 Stephen Hammann

Stephen Hammann Health Physicist Commercial and R&D Branch Division of Nuclear Materials Safety

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SUNSI Review Complete: SHammann
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