

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE CONVERSATION RECORD

Date: March 29, 2016

Time: 2:00 PM

Mail Control
or Report No(s).

590303

License No(s).

06-08544-01

Docket No(s).

030-01274

Name of Licensee: Danbury Hospital

Name of Participant(s): Ruth Shanley, Radiation Safety Coordinator
Janice Nguyen

Telephone No. (203) 739-7182

Subject: Request for additional information regarding Sirtex proctoring information for Fatejeet Sandhu, M.D.

(NOTE: This will be used as the
Documents Title in ADAMS)

I was assigned the notification action under mail control number 590303, which is the documentation of the three proctored SIR-Spheres cases by Fatejeet Sandhu, M.D. I need some additional information in order to accept the notification. The short letter from Adam Paster, the Sirtex Regional Sales Manager, doesn't list Dr. Sandhu's name (just that a Sirtex representative was on-site for 3 proctored cases). I need something that would indicate that Dr. Sandhu performed three cases under the manufacturer's representative and now has the training and experience to function independently as an authorized user for SIR-Spheres. Sirtex has previously used a form called the Proctoring Evaluation Form. The Sirtex proctor would fill out the form for each proctored case (so there would be 3 forms total for each authorized user), and then they have a statement at the end (on page 3 of 3) saying they are qualified, no more proctoring is required, etc. I asked that Ms. Shanley contact Adam Paster and request the three Proctoring Evaluation Forms for Dr. Sandhu. I also mentioned that she could do a google search on Sirtex Proctoring Evaluation Forms to find some examples of the documents. I just had a fellow license reviewer contact Adam Paster to get the additional information for another authorized user at another facility, so he should know exactly what we need. I requested that Ms. Shanley submit the additional information to me by email or fax, and reference mail control number 590303.

Action Required: Wait for additional information and then process license notification.

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Sensitive - Security-Related

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Immediate Release

Normal Release Date:

Delayed Release Date:

SUNSI Review Completed By: Janice Nguyen / RA /

Document Accession #: _____