

U.S. NUCLEAR REGULATORY COMMISSION		Conversation Date: 11/22/2004	
TELEPHONE CONVERSATION RECORD		Time: 1:30 pm	
Mail Control No.: 135704	License No.: 37-30654-01	Docket No.: 030-35771	
Licensee/Applicant Participant(s): Jane Fisher (RSO)	Organization: Tristan Associates	Telephone No.: 717-909-4160	
Person(s) Calling: Joe Nick			
Subject: Request for Additional Information			
<p>Summary:</p> <p>I spoke to the licensee's RSO on 11/22/04 and asked for additional information regarding the recent letter requesting an amendment for the NRC material license (dated 9/17/04).</p> <p>The licensee's letter request the addition of two individuals as authorized users for material permitted under 10 CFR Parts 35.100, 35.200, and 35.300. However, the licensee did not provide adequate documentation regarding the individuals' qualifications for therapeutic use under Part 35.300. For treatment of thyroid carcinoma (per 35.934), the individuals require 80 hours of classroom and laboratory training; and supervised clinical experience under the supervision of an authorized user that includes the use of I-131 for the treatment of thyroid carcinoma in 3 individuals. For all uses permitted by 35.300 (per 35.930), the individuals require certification by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology. The licensee had submitted certifications from American Board of Radiology for diagnostic radiology. The RSO stated that she was not sure if the individuals had the experience required; therefore, the authorization for 35.100 and 35.200 would be adequate for this amendment. The RSO also stated that the additional information would be gathered and submitted in the future.</p> <p>I also verified that the applicant had planned to request 2.0 curies as the maximum possession limit for any radiopharmaceutical identified in 10 CFR 35.300, since this seemed to be a very large amount. The RSO stated that amount requested was correct, and although it was higher than normal, they wanted to be prepared for many patient treatments.</p> <p>I told the RSO that I had the information that was necessary and the amendment would be issued in the near future.</p>			
Action Required/Taken:			
Prepared By: Joe Nick		Date: 11/22/2004	