From: Michelle Simmons
To: BSeifert@srhs-pa.org
Date: Mon, Dec 19, 2005 3:13 PM
Subject: Request for additional information (License Number 37-01626-04)

Mail Control Number 137840
Docket Number 03013670
License Number 37-01626-04

Your request did not indicate which authorizations you are requesting for Dr. Panicker. Based on his training in Diagnostic Radiology and caselist of radiopharmaceutical therapy patients, you may wish to request 35.100, 35.200, and 35.300. Please provide the following additional information to show that Dr. Panicker meets the requirements of 10 CFR 35.290 and 35.390. Please provide this information as soon as possible. Please fax your signed response to 610-337-5269, referencing mail control 137840. When you send the fax, you may wish to leave a voicemail or e-mail message to alert me to look for it.

Please send an e-mail to confirm receipt of this message.

Please be advised, due to changes in NRC regulations, the ABR certification submitted for Dr. Panicker is not recognized by NRC under 10 CFR Part 35 at the present time.

Provide documentation that Dr. Panicker has completed:

For 35.100 and 35.200
(a) 700 hours of training and experience including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include classroom and laboratory training in the following areas of Radiation physics and instrumentation; Radiation protection; Mathematics pertaining to the use and measurement of radioactivity; Chemistry of byproduct material for medical use; Radiation biology; and

Work experience, under the supervision of an authorized user, who meets the requirements in 10 CFR 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or equivalent Agreement State requirements, involving Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; Calculating, measuring, and safely preparing patient or human research subject dosages; Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; Using procedures to safely contain spilled radioactive material and using proper decontamination procedures; Administering dosages of radioactive drugs to patients or human research subjects; and Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Provide written attestation, signed by a preceptor authorized user who meets the requirements in 10 CFR 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, and stating that Dr. Panicker has satisfactorily completed the requirements in paragraph 10 CFR 35.290(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

For 35.300, indicate the categories requested and provide the following:
(a) 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include classroom and laboratory training in the following areas of: Radiation physics and instrumentation; Radiation protection; Mathematics pertaining to the

use and measurement of radioactivity; Chemistry of byproduct material for medical use; and Radiation biology; and

(b) Provide work experience, under the supervision of an authorized user who meets the requirements in 10 CFR 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in 10 CFR 35.390(b) and must also have experience in administering dosages in the same dosage category or categories (i.e., 10 CFR 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; Calculating, measuring, and safely preparing patient or human research subject dosages; Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required; Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; 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 Parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Provide written attestation that the individual has satisfactorily completed the requirements in paragraphs 35.390(a)(1) and (b)(1)(ii)(G) or (b)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in 10 CFR 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in 10 CFR 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., 10 CFR 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.

For the individual(s) signing the written attestation(s), document their status as authorized user for 35.200 and 35.300 by providing one of the following: license number of a limited scope NRC license listing them as authorized user, copy of an limited scope Agreement State license listing them as authorized user, or copy of permit issued under a broad scope NRC or Agreement State license documenting their authorized user status.

We appreciate your patience and attention to detail in documenting compliance with these complex, new training and experience requirements for authorized users.

Thank you for your help. If you have any questions, you may send an e-mail or call me at 610-337-6921.

Michelle Simmons
Health Physicist
US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Phone: 610-337-6921
Fax: 610-337-5269

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Subject: Request for additional information (License Number 37-01626-04)
Creation Date: Mon, Dec 19, 2005 3:13 PM
From: Michelle Simmons

Created By: MRS5@nrc.gov

Recipients
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Files	**Size**	**Date & Time**
MESSAGE	8954	Monday, December 19, 2005 3:13 PM
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Options

Expiration Date:	None
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard