

**From:** Sandra Gabriel  
**To:** karen.stewart@camc.org  
**Date:** Fri, May 20, 2005 5:25 PM  
**Subject:** Request to amend NRC license, mail control 136791

Reference: Charleston Area Medical Center  
License: 47-15473-01  
Docket: 03009164  
Mail Control: 136791

To: Karen Stewart  
Associate Administrator for Medicine Services  
Charleston Area Medical Center  
3200 MacCorkle Avenue, SE  
Charleston, WV 25304

This is in reference to the letter from Subhash Danak dated March 29, 2005 requesting to amend Nuclear Regulatory Commission License No. 47-15473-01.

1. The letter requested to add Premkumar Raja, M.D. as an authorized user for byproduct material permitted by 10 CFR 35.400, 35.600, and 35.1000. Please note that your current license does not authorize any uses under 35.600, therefore we will authorize Dr. Raja for 35.400 and intravascular brachytherapy licensed under 35.1000.

2. The letter requested to add Stafford G. Warren, M.D. as an authorized user for byproduct material permitted by 10 CFR 35.100 and 35.200. The credentials submitted for Dr. Warren do not meet the requirements of 10 CFR 35.290(c) that were in effect on the date of this request. The letter provided a certificate of attendance at a 50-hour Nuclear Physician Licensing course (with no listing of topics covered), and two letters describing supervised experience in reading and interpreting nuclear studies. Note that 35.290(c) requires radioactive materials handling experience, but does not address clinical interpretation of patient studies.

The requirements of 10 CFR 35.290(c) in effect on the date of your request were:

(1) Completion of 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct materials for imaging and localization studies. The training and experience must include, at a minimum:

(i) Classroom and laboratory training in 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

(ii) Work experience under the supervision of a qualified authorized user involving ordering, receiving, and unpacking radioactive materials safely and performing the related surveys; calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct materials; using procedures to safely contain spilled radioactive material and using proper decontamination procedures; administering dosages of radioactive drugs to patients; 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

(2) Provision of written certification, signed by a preceptor authorized user who meets the requirements in 35.290, 35.390, or equivalent Agreement State requirements that the individual has satisfactorily completed the requirements in (1), above and has achieved a level of competency sufficient to function as an authorized user for the medical uses authorized

under 35.100 and 35.200.

Based on these requirements, in order to approve Dr. Warren as an authorized user, you must submit::

a) Documentation of the topics covered in the 50-hour class, confirming that each of the topics listed above in (1)(i) was included;

b) Documentation of 650 hours of work experience under the supervision of an authorized user confirming that each of the activities listed above in (1)(ii) was included; and

c) The written certification described above in (2)

NRC Form 313A may be used to document this information, however use of this form is not required.

Please note that the requirements of 10 CFR 35.290 changed on March 30, 2005. If you choose to withdraw the current request and resubmit it in the future, it will be necessary for Dr. Warren to meet the new requirements which include a minimum of 80 hours of classroom and laboratory training.

3. We will make some minor updates in your license with this amendment, reserving major updates for your license renewal later this year. For byproduct material permitted by 10 CFR 35.300, NRC's current practice is to list a maximum possession limit for all materials, not limited to I-131. Is your current limit of 1.5 Ci for I-131 sufficient to cover all material permitted under 35.300?

Please provide this information within 30 days. You may fax your response to 610-337-5269, referencing mail control 136791. Please notify me when the fax is sent so I will know to look for it. You may e-mail or call me with any questions.

Thank you,

Sandy Gabriel  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety  
NRC Region I  
610-337-5182

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