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September 22, 2003

U.S.N.R.C.
Region II
61 Forsyth Street, NW, Suite 23 T 85
Atlanta, GA 30303-3415

Re: License Number 47-25351-01

To Whom It May Concern:

Please amend our materials license to reflect the following changes:

1. Add Mark Xenakis, MD as an authorized user on our byproduct material license for materials identified in 10 CFR 35.100 and 35.200. Verification of Dr. Xenakis' training and experience is attached for reference.

Thank you for your attention to this matter.

Sincerely,

Steven Walter, M.D.
RSO
Authorized User
General Manager and CEO

WAKE FOREST
SCHOOL of MEDICINE
THE BOWMAN GRAY CAMPUS

Kathryn A. Morton, M.D., Professor of Radiology
DIVISION OF RADIOLOGIC SCIENCES
DEPARTMENT OF RADIOLOGY
NUCLEAR MEDICINE SECTION

9/10/03

Dear Colleague,

As the Director of Nuclear Medicine at Wake Forest University School of Medicine, I have clinical, academic and administrative oversight of Nuclear Medicine, which includes Nuclear Cardiology. I am also an Authorized user under the Nuclear License for Wake Forest University Health Sciences (#0340158-1, expires Dec 31, 2006). I am the authorized preceptor for Nuclear Cardiology training for the Cardiology Fellows at this institution. This communication is to confirm that Mark Xenakis, MD, has successfully completed all training requirements set forth by the Nuclear Regulatory Commission guidelines section §§35.290, paragraph c (1). He has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under the NRC guidelines §§35.100 and 35.200.

Dr. Xenakis received 6 months of training in Nuclear Cardiology, which was completed on 6/30/03, and was received as part of his cardiology fellowship at Wake Forest University Health Sciences Center, Winston-Salem, NC. The Nuclear Cardiology educational requirements were completed during a combination of rotations that included dedicated nuclear cardiology, echocardiography and research. The specifics of Dr. Xenakis' training are as follows:

A. Dr. Xenakis has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience included a minimum of the following:

1) Classroom and laboratory training in the following areas--

   a) Radiation physics and instrumentation;

   b) Radiation protection;

   c) Mathematics pertaining to the use and measurement of radioactivity;

   d) Chemistry of byproduct material for medical use;

   e) Radiation biology

2) Work experience, under the supervision of authorized users (Kathryn A. Morton, MD, Paige B. Clark, MD, Nat E. Watson, MD and James D. Ball, MD) which meet the requirements in §§ 35.290 or 35.390, involving--

   a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

   b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c) Calculating, measuring, and safely preparing patient or human research subject dosages;

d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f) Administering dosages of radioactive drugs to patients or human research subjects; and

g) 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

B. In addition, Dr. Xenakis has completed training in the clinical aspects of Nuclear Cardiology, which has included the following:

1) Interpretation of over 334 studies [(mostly gated SPECT myocardial perfusion scans, but also PET myocardial viability scans and radionuclide ventriculograms (MUGA's)].

a) Review of over 250 myocardial perfusion scans with angiographic correlation.

b) First-hand performance (with supervision) of all aspects of 25 nuclear cardiology exams, including:

c) preparation of nuclear radiopharmaceuticals

d) camera quality control, set up and calibration

e) patient preparation, dose administration

f) scan acquisition and processing

g) interpretation and reporting results of exams

In addition to the above formal training, Dr. Xenakis also obtained significant additional training by self study and attendance at lectures in nuclear cardiology at the American College of Cardiology Scientific Sessions and the American College of Cardiology Board Review.

I am pleased to confirm that Dr. Xenakis is competent in all aspects of Nuclear Cardiology and is qualified to serve as an authorized user. I would be pleased to include him as a colleague or partner in my own practice. If you have any additional questions, please feel free to contact me directly.

Kathryn A. Morton, MD
Director of Nuclear Medicine and PET
Wake Forest University Health Sciences Center
Phone 336-716-3099, FAX 336-716-5639, Pager 336-806-8236, Email kmorton@wfubmc.edu