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August 4, 2010

Mr. Kevin Null  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: Materials License 21-11315-02, Request for amendment dated May 21, 2010

Dear Mr. Null,

The purpose of this letter is to provide the additional information you requested pertaining to our request for license amendment (letter dated May 21, 2010).

1. The materials requested (a  $^{137}\text{Cs}$  sealed calibration source and a  $^{99}\text{Mo}/^{99m}\text{Tc}$  generator) will not be used in research on humans, nor will radioactive materials be administered to humans. The materials requested will be used for laboratory research as defined in 10 CFR 30.4, including animal studies, following the restrictions of our materials license. The specific proposed studies that prompt the need for the  $^{99}\text{Mo}/^{99m}\text{Tc}$  generator involve tissue distribution studies in animal models for drug therapeutics.
2. The possession limit requested for  $^{137}\text{Cs}$  (in sealed source form) is 0.250 mCi, which is the stated activity of the source to be obtained. The requested possession limit associated with the  $^{99}\text{Mo}/^{99m}\text{Tc}$  generator is 32 Ci of  $^{99}\text{Mo}$  (to accommodate a maximum of two generators at the facility at any one time) and 32 Ci of  $^{99m}\text{Tc}$  to accommodate the maximum amount in secular equilibrium and in use at any given time.
3. Radioactive waste produced in utilization of the  $^{99}\text{Mo}/^{99m}\text{Tc}$  generator and remaining activity in spent generators will be included in our decay in storage disposal process. Generators containing tungsten or depleted uranium shielding will be returned after decay of the contents to the supplier, as required by the purchase agreement.

4. Generators not in use (either prior to use, post-use, or when not being utilized) will be stored in an appropriately shielded area or container, located either in the storage area adjacent to the Molecular Imaging facility, or in the Radioactive Waste Storage Building. Both locations are within access-controlled radiologically restricted areas. Additional shielding in the form of lead bricks and sheet is available for use as necessary. For generators in use, elutions will be performed using a Technestat auxiliary shield and Duosafe elution shield (or similar functionally equivalent shielding with appropriate adapters). Dose calibration and handing of the eluent in the elution vial will be performed using our existing L-block shield/dose calibrator shield system. Syringes will be filled and utilized using a vial shield and a syringe shield as required.

All storage and use area shielding and access control is designed to maintain radiation doses to occupationally exposed personnel and members of the public as low as reasonably achievable. Please contact me at 269-668-3336 extension 2050, if there are any questions, or if further information is required.

Sincerely,



Richard Granberg, CHP  
Radiation Safety Officer  
MPI Research, Inc



*FAX COMMUNICATION*

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TO: MR. KEVIN NULL

COMPANY: U.S. NUCLEAR REGULATORY COMMISSION

FROM: RICHARD GRANBERG

DATE: 8/4/2010

RE: AMENDMENT TO LIC. 21-11315-02, DTD 5/21/2009  
ADDITIONAL INFORMATION