UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

December 8, 2006

Radiology Associates, Prof. L.L.C.
ATTN: Rhonda Berger
Lead PET/CT Technologist
P.O. Box 8130
Rapid City, SD 57709-8130

SUBJECT: RESPONSE TO LETTER DATED NOVEMBER 16, 2006

Dear Ms. Berger,

This is in regards to the subject letter in which you requested confirmation that the U.S. Nuclear Regulatory Commission (NRC) does not regulate the proposed elements of your positron emission tomography (PET) imaging service or any of the calibration sources, as listed in the attachment to your letter. The NRC, at this time, does not regulate PET or the calibration sources identified in your letter. However, as discussed telephonically, the NRC will regulate accelerator-produced radioactive materials for specific uses in the near future.

President Bush signed into law on August 8, 2005, the Energy Policy Act of 2005, expanding the NRC's jurisdiction from the current definition of byproduct material, to include accelerator-produced radioactive materials and discrete sources of radium 226 (Ra-226). The current definition of byproduct material is any material that was made radioactive by exposure to the radiation in a nuclear reactor. The Energy Policy Act will therefore change the definition of byproduct material in Section 11e of the Atomic Energy Act, to incorporate Ra-226 and accelerator-produced radioactive material (NARM) for commercial, medical, and research use only. Some examples of NARM include sodium-22, cobalt-57, gallium-67, and fluorine-18.

Additional information regarding the proposed rulemaking and transitory plan may be located on the NRC Website at: http://ruleforum.llnl.gov. Then select "Advanced Notices of Proposed Rulemaking" and select "Requirements for Expanded Definition of Byproduct Materials" dated 7/28/06.

The NRC published waivers to states on August 31, 2005, to allow the states to continue to regulate the affected material and allow persons engaged in those activities to continue their activities. The waivers are effective until August 7, 2009; however, they may be terminated sooner, depending on the effective date of the final regulation. The NRC is currently developing regulations for the expanded jurisdiction. Publication of the final rule is expected sometime during 2007. The effective date of the final rule will be 60 days from the date that the final rule is published in the *Federal Register*. Tentatively, new license applications would be required within one year following the effective date or waiver termination.

If you determine that you will use calibration sources that were made radioactive by exposure to the radiation in a nuclear reactor, such as cesium-137 or cobalt-60, then you will need to apply for an NRC radioactive materials license to use such byproduct material, unless they are exempt concentrations or exempt quantities as outlined in 10 CFR 30.14 and 10 CFR 30.18, respectively.

If you have any further questions regarding this matter or working in NRC jurisdiction, please contact me at (817) 276-6552.

Sincerely,

/RA/

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

bcc:
RSBrowder
JDCook
ADAMS

SUNSI Review Completed: RSB ADAMS: ■ Yes ☐ No Initials: RSB
■ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ■ Non-Sensitive

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