UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

August 29, 2012

Docket No. 03036120 License No. 19-30771-01
Control No. 578109

Charles Sabatos
Acting Executive Officer
Department of Health & Human Services
Food and Drug Administration
Harvey W. Wiley Building, HFS-657
5100 Paint Branch Parkway
College Park, MD 20740

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 578109

Dear Mr. Sabatos:

This is in reference to your application dated August 1, 2012 requesting to amend Nuclear Regulatory Commission License No. 19-30771-01. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than Michael Spady. Please confirm that you desire to become a limited scope licensee from a broad scope license. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

2. On the mailing address written on the application, the letters “HFS-657” were left off. Please confirm that you want “HFS-657” removed from the mailing address.

3. On the list of proposed Authorized Users, Badaruddin Shaikh and Badar Shaikh names are very similar. There was not a resume attached for Badaruddin Shaikh. Please confirm this is the same person or submit education and experience for Badaruddin Shaikh.

4. With the exception of Michael Spady, the resumes for the proposed authorized users, rarely discussed the radionuclide that the person had experience utilizing. Also, it was unclear if the proposed authorized users were to be authorized for all the radionuclides authorized on the license. NUREG-1556, Volume 7, “Consolidated Guidance About Material Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,” states in section 8.7.2 to provide the name of each proposed Authorized User with the types and quantities of licensed

material to be used along with information demonstrating that each proposed Authorized User is qualified by training and experience to use the requested licensed materials. Please submit the name of the proposed Authorized User, the radioisotopes to be authorized, and the experience related to using that radioisotope.

5. Section 8.8 of NUREG-1556, Volume 7, "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," states that the applicant to describe the radiation safety training program including topics covered, groups of workers, assessment of training, qualification of instructors, and method and frequency of training. For unsealed materials, it would be unusual for users and ancillary personnel to not receive any training even for those not required by 10 CFR 19.12. You submitted your training program for those who qualify for 10 CFR 19.12(a) but not for those that may not qualify for 10 CFR 19.12(a). In section 10.1 or your application, you do state users will receive initial radiation safety training. Please reassess, the need for training of ancillary personnel who enter areas controlled by this program. Please state the qualification of instructors, method and frequency of training, and assessment of training.

6. Section 8.9 of NUREG-1556, Volume 7, "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," states for facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. No room diagram was submitted in the application. Please submit an example of a room diagram.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 578109. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We

strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Michael A. Spady, Radiation Safety Officer

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