**The ALARA Group**
***Accreditation, Licensing, and Radiological Associates***
***Specialists in Cardiovascular Laboratory Accreditation***
***P.O. Box 583***
***Feasterville, PA, 19053***
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August 24, 2006

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03037319
37-31179-01

Dennis Lawyer
Nuclear Regulatory Commission
Division Of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King Of Prussia, Pa 19406-1415
Fax # 610-337-5393
Phone 610-337-5366
Mail Control # 139254

Re: Medical Use Radioactive Materials License Application

Dear Mr. Lawyer,

As per our conversation yesterday, I am requesting changes to the radioactive materials license application for Riaz Baqir, MD, FACC, Cardiovascular Solutions, Inc, as outlined in the following pages. All changes are highlighted in bold.

Thank you for your thorough review of Dr. Baqir's license application. If you have any questions, or need any additional information, please do not hesitate to call me at (215) 436-1412.

Cordially,

Kevin F. Smith, MPH, PhD
Document Preparer
Senior Specialist, The ALARA Group
Consultant Radiation Health Physicist, Cardiovascular Solutions, Inc.

Cc: Jeffrey Mandler, President, Cardiovascular Solutions
File

8/24/06

Enclosures

139254

Item 7: Radiation Safety Officer

**Kevin F. Smith, MPH**

**Copy of City of New York radioactive materials license for The Brooklyn Hospital Center, Brooklyn, NY, on which I was named as Radiation Safety Officer, through 2003.** Also attached is the section of my CV, which lists my radiation safety experience:

Radiation Safety and Health Physics Summary
Kevin F. Smith, MPH

Employment

Feb. 2003 – Present Albert Einstein Medical Center, Philadelphia, Pennsylvania
Radiation Health Physicist, Department of Radiation Safety.

1989-2000 The Brooklyn Hospital Center
Medical Physicist, Technical Coordinator, Radiation Safety Officer
Radiation Safety Officer for institution. Responsible for medical and health physics applications in a multi-camera department with SPECT and coincidence detection. Managed computing activities for the entire department. Performed quality control on imaging systems. Clinical coordinator for two nuclear medicine technology academic affiliations. Provided technical expertise regarding equipment purchases.

Education

1992 Columbia University, New York
Master of Public Health, Applied Medical Physics/Health Physics

1986 Manhattan College, New York
Bachelor of Science, Radiological Sciences

Radiation Safety Officer Appointments

1989-2000 License #: 91-2924-01, The Brooklyn Hospital Center, Brooklyn, N.Y.

1998-Present License #: 91-3129-01, Enigma Laboratories, Brooklyn, N.Y.

1996-Present License #: 52-3102-01, Kumar Shah, M.D., Brooklyn, N.Y.

Licenses

August, 2003 Licensed as a Nuclear Medicine Physicist in the State of New York
License #: 000084, Expires July 31, 2009

August, 2003 Licensed as a Health Physicist in the State of New York
License #: 000078, Expires July 31, 2009

Health Physics Consultation
Consultant Health Physicist for seven nuclear medicine laboratories in the State of New Jersey, two in the State of New York.

The RSO will bear responsibilities for the radiation safety program. The RSO may delegate the responsibility of performing the required radiation safety tasks to the qualified nuclear medicine technologist. However the RSO is responsible to review the results of all radiation safety testing.

Responsibilities of the RSO

- Oversee the ALARA Program as outlined above.
- Oversee the personnel-monitoring program.
- Assure that qualified, licensed individuals will carry out the use of any radioactive isotope in a facility capable of handling radioactive materials.
- Assure that all safety standards are met as outlined by the Nuclear Regulatory Commission and Pennsylvania Department of Environmental Protection.
- Assure that records of receipt, use, storage, and disposal of radioactive isotopes are kept in accordance with regulatory requirements.
- Review the records of removable contamination surveys and monitoring of all areas within the laboratory.
- Assure that the laboratory equipment is properly calibrated.
- Make recommendations for improvement of radiation safety practices.
- Instruct individuals in procedures to minimize exposure to radiation sources.
- Receiving, delivering, and shipping all radioactive materials coming to or leaving the institution.
- Supervision and coordination of the waste disposal program, including the keeping of waste storage records.
- The storage of all materials not in current use.
- Performing leak tests on all sealed sources.
- The authority to immediately terminate a project involving radioactive materials, which is found to be a threat to health or property.
- The authority to upgrade/replace survey meters, scaler rate meter, well counter, dose calibrator, and other health physicis/radiation safety instrumentation when needed.
- **The authority to upgrade/replace survey meters, scaler rate meter, well counter, dose calibrator, and other health physicis/radiation safety instrumentation when needed.**

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

CARDIOVASCULAR SOLUTIONS, INC, POLICY FOR TRAINING / IN-SERVICE EDUCATION

It should not be assumed that radiation safety instruction has been adequately covered by prior professional or occupational training. In addition to radiation workers, ancillary personnel whose duties may require them to work in the vicinity of radioactive material need to be informed about radiation hazards and appropriate precautions.

Personnel will be instructed:

1. before assuming duties with, or in the vicinity of, licensed material;
2. during annual refresher training;
3. whenever there is a significant change in duties, regulations, or the terms of the Radioactive Materials License and Radiation Safety Program.

Training and instruction should be commensurate with the employee's duties and responsibilities. The guidelines outlined in Appendix J of NUREG 1556, Volume 9 (10/02) will be used.

Instruction Categories

1 Radioactive Materials Use
2 Radiation Detection and Measurement
3 Time Distance and Shielding
4 Receipt and Security of Radioactive Materials
5 Personnel Monitoring Program
6 ALARA Program
7 Emergency Procedures

Personnel who will receive training:

1. Nuclear Medicine Technologists, Attendings, Nurses, and Stress Testing Personnel, before assuming duties with, or in the vicinity of, licensed material.

**Training will be provided by the RSO, Authorized User or qualified Health Physicist.**

ITEM 9: RADIATION MONITORING INSTRUMENTS

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

**Survey Meter will be calibrated annually by a qualified company that performs these services routinely and is recognized as an approved vendor.**

**Survey Meters:**

**Ludlum 14C Survey Meter with energy compensated probe.**

**Ludlum Model 3 Survey Mater.**

ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

The laboratory will also possess:

**One Dose Calibrator: Atomlab 100 Dose Calibrator**

The following tests will be performed on the dose calibrator:

At Installation, and after repair, or relocation:

Geometry, by Physicist

Annual:

Accuracy, by Physicist

Quarterly:

Linearity, by Physicist, using Calicheck

Daily:

Constancy, by technologist
Cross Channel Check, by technologist.

**Ludlum 2200 Scaler Rate Meter with Well Counter**

Annual: Efficiency, by Physicist

Daily: Constancy, by technologist

ITEM 10: OCCUPATIONAL DOSE

Nuclear medicine technologists, attending physicians, stress lab personnel, and other individuals working in either the imaging room, stress lab, or prep room, are likely to exceed 10% of the allowable limits in 10 CFR Part 20.

These individuals will be issued personnel dosimeters (badges).

Nuclear medicine technologists will also be issued ring badges.

**Dosimeters will be processed by a qualified company that performs these services routinely and is recognized as an approved vendor.**

For individuals working in the reception area and waiting area, we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002."

Likewise, for members of the public who accompany patients undergoing nuclear cardiology procedures, and other visitors to the lab who are not going to receive radioactive administrations, we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002."