

NUCLEAR CARDIOLOGY IMAGING, PSC

May 22, 2012

Lester Tripp
USA, Nuclear Regulatory Commission
Region I Office
2100 Renaissance Blvd, Suite 100
King of Prussia, Pennsylvania 19406-2713

NUCLEAR CARDIOLOGY IMAGING, P.S.C., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 577228

Dear Mr. Tripp:

I am submitting the information requested for your review of the Nuclear Cardiology Imaging, P.S.C. material license number 52-25558-01 of communication dated May 10, 2012.

1. In support of your request to authorize Dr. Devarie for materials permitted under 10 CFR 35.100 and 200, please provide one of the following, as applicable:
 - a. Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an authorized user for the uses requested; or
 - b. Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subpart D; or
 - d. Description of the training and experience identified in 10 CFR Part 35 Subparts D, demonstrating that the proposed authorized user is qualified by training and experience for the use requested; and

- e. Written certification, signed by a preceptor physician authorized user, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an authorized user for the medical uses authorized has been achieved; and
- f. If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

NRC Form 313A (attached) may be used to document this information. Please note that if the board certification, or training and experience, was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

Answer:

Dr. Marcus Devarie has never been named as an Authorized User on previous license for the uses requested. However, Dr. Devarie will not apply as an AU for this license. Please continue your review for the authorization of Dr. Juan Fontáñez Nieves as AU in this license. All documents regarding training and experience have been already submitted.

- 2. The licensee has requested that Jossian Pagán be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:
 - a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

Answer:

In accordance with 10 CFR 35.24, we provide the RSO sufficient authority, organizational freedom, time, and resources to perform his duties and responsibilities related to the radiation safety program to ensure that radioactive materials are used in a safe manner. Also has the authority to terminate any activity in which health and safety appear to be compromised without consulting with the Management if required. The RSO has no disciplinary authority which shall reside instead with the Management or the Administration Representatives of the facility. Attached you will find a copy of the RSO Delegation of Authority.

- b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

Answer:

The consultant-RSO will have totally support and economical resources to facilitate the objectives of the radiation safety program and related regulatory requirements.

- c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

Answer:

Typically, RSO duties and responsibilities include ensuring the following:

- Review of actual NRC License Material.
- Unsafe activities involving licensed material are stopped;
- Evaluate monthly exposure reports of the Nuclear Medicine personnel. Ensure that radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device Registry (SSDR) certificate(s), and the manufacturer's recommendations and instructions;
- Ensure that the terms and conditions of the radioactive materials license are met and that the license is amended for changes in the use of radioactive material, responsible individuals, or commitments to the Nuclear Regulatory Commission (NRC) in the licensing process;
- License Applications, Renewals, Terminations, Amendments and Notifications
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material including ancillary personnel;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and

- documented. Monthly inspection will be performed and followed by a report;
- Regulatory inspections/enforcement actions assistance
 - If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
 - Provide assistance for the management of emergency, accident, spill, or exposure situations.
 - Maintain a safety environment free of radioactive contamination.
 - Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
 - Licensed material is disposed of properly and documents are maintained;
 - Appropriate records are maintained for NRC review;
 - An up-to-date license

In order to fulfill the duties and responsibilities, the RSO will visit the facility on monthly basis to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 10 CFR 35.24 and when ever necessary. He will also be available during the weekends and will have full access to the Nuclear Medicine Laboratory to evaluate all activities involving the use of byproduct material.

- d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

Answer:

The contact person on this facility when the RSO is not on-site or on his absence will be the AU or the Nuclear Medicine Technologist. They are trained in the safe use of license material and also have the knowledge of the Radiation Safety Program and the ALARA concept. They are available on-site to assist in day-to-day radiation safety issues and can reach the RSO by phone for assistance at any time.

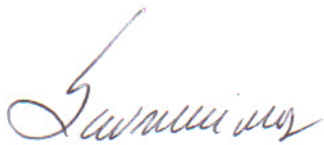
- e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

Answer:

The RSO will be available by phone to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements. The amount of time it will take him to arrive at the facility to respond to an emergency will be approximately 15 to 30 minutes. He will also be available by phone to assist in an emergency.

If there is any question regarding this renewal, please contact me for any additional information at phone number (787) 722-2932

Cordially,

A handwritten signature in cursive script, appearing to read "Marcos Devarie".

Marcos Devarie, M.D.
President
Nuclear Cardiology Imaging, P.S.C