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To: <slg2@nrc.gov>
Date: 08/24/2007 12:30:53 PM
Subject: Letter from David Rhoe about 35.200

52-25430-03
03036911

Sandy,

Attached you will find my request. In addition, there are several physicians that would like to do the same thing. i.e., one nuclear medicine laboratory would have the generator and all the users listed on that license and then perform a license transfer to their own private labs. Please address this issue as a single laboratory and also as a multi-laboratories.

Thanks!!!

David

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David Rhoe
CRMI 52-25430-03
Paseo de la Fuente
D-4 Calle Tivoli
San Juan, PR 00926
787-245-7248

August 24, 2007

Sandy Gabriel
US NRC, Region I
475 Allendale Road
King of Prussia, PA 19406

RE: 35.200, the use of a Tc-99m generator under an authorized user.

Dear Ms. Gabriel:

I would like clarification on providing invoices to insurance companies.

Background

Currently I have a NRC license for a nuclear medicine laboratory with my wife (Dr. Sandra Gracia-López) as the authorized user. As of September 1, 2007, several prices for unit doses are increasing from 22 to 50 percent, which is forcing facilities to reconsider using Tc-99m generators or taking a financial loss until insurance companies increase their rates. The problem with returning to the Tc-99m generator is that the reimbursement rates are up to 40% lower than the rates from a distributor, which is still forcing a facility to take a loss.

Proposal

We would like to use the Tc-99m generator in-house and also produce our own cold-kits. This will allow us to offset the increase cost that will be going into effect in September 2007. We plan to have the generator delivered to the nuclear medicine laboratory, milk the generator, prepare our own cold kits, reconstitute the kits with the Tc-99m, and make unit doses for both of our laboratories (Aibonito and Cayey). I am planning to purchase an automatic dose-dispensing unit that is capable of "milking the generator", reconstitute the cold-kits, drawing each unit dose, and placing the unit dose in a shipping container to minimize all radiation exposures. I have talked with the NRC before regarding this matter and several people have indicated this would not be a problem. However, the insurance reimbursement has now created a new twist.

Problem

For insurance companies to pay the reimbursement rates listed for a distributor, I must provide an invoice with the unit doses. I have talked to a lawyer in Puerto Rico and the above proposal does not violate any law or regulation however, he has advised me to get

written approval/clarification from the NRC so that this will not be an issue during future inspections.

Your prompt attention to this matter would be greatly appreciated. If you have any questions or concerns, please feel free to contact me at the number above.

Sincerely,

A handwritten signature in black ink, appearing to read "David Rhoe", with a stylized flourish at the end.

David Rhoe, MS, WSO-CHME, WSO-CSI