



DEPARTAMENTO DE CIENCIAS RADIOLOGICAS  
RADIOLOGICAL SCIENCES DEPARTMENT

December 1, 2002

Mr. Douglas Collins, Director  
Division of Material Safety  
Nuclear Regulatory Commission

Dear Sir:

This is in response to the letter dated November 8, 2002 in relation to the inspections and investigation conducted at the University of Puerto Rico, Medical Science Campus, on February, March and August 2001.

An apparent violation in which my personnel and I were involved has been proposed. Specifically the cited apparent violation refers to the failure to perform daily surveys in areas where radiopharmaceuticals are administered. Definitely I do not agree with the statement that charges me and the UPR with a deliberate and willful violation to NRC requirements. We do not believe that the apparent violation occurred, nor was there a deliberate or willful violation of NRC regulations. I will proceed with a detailed and sequential exposure of the fact that led to us to the conclusion stated above.

1. On April 2000, the RSO asked for an amendment to the License 52-01946. The amendment requested a change in the receipt, inspection and survey of radioactive packages. Neither the Radiation Safety Committee nor the nuclear medicine personnel were informed of this change on the license before it was submitted to NRC.
2. In August 2001, one of the Radiation Safety Technician suggested the RSO in a letter that areas in Nuclear Medicine for which a weekly survey was required were changed to daily surveys, and therefore included under license section 10.4 (B) 17.

On September 27, 2001, the RSO sent a letter requesting the use of a specific format designed by their office for the record of the packages surveys. However, I should point out that packages measurements and all the required data were adequately kept by the nuclear medicine personnel and no citation was pointed by the NRC inspectors in this respect.

In the same letter, the RSO mention that surveys in areas of radiopharmaceutical preparation should include the imaging areas (in addition to the surveys done in the Hot Room). Regular, daily, radiation surveys were done in the Hot Room, as stated in our license, Attachment 10.4 (B)17. The weekly evaluation of the laboratory areas were also done regularly by the RST, as required by the license, Attachment 10.12. This has always been part of the RSO office. In fact Mr. Perez-Bobonis, the previous RSO, did the surveys himself during the time he worked as RSO.

The change presented by the RSO in that letter in relation to the survey areas and the frequency of surveys represents a change in the section 10.4(B) 17 of the license and requires an amendment to the license which was not presented to the RSC. To my knowledge, no change has been approved to this part of the license. No amendment has been submitted to the RSC or the licensee for this section.

In spite of the above, when the issue was brought to my attention by the end of 2001, I immediately called Dr Heriberto Torres, the RSO, to a meeting. We discussed the need for a meeting with the nuclear medicine technologist and the RST for a solution on the issue. This meeting was held in my office, with Dr H. Torres, the supervisor of the nuclear medicine technologist and me. Dr Torres told us he was going to get a solution. I understood from that statement he was going to take a proactive position and provide us with a final recommendation.

From September to January 2002, the subject was not brought to my attention again. It was neither brought by the RSO as an issue to be resolved by the RSC at its meeting held on December 2001. The Radiation Safety Office personnel visited our areas regularly during the same period and never gave an official notification to our supervisor or to me regarding this situation.

3. On January 25, 2002, Dr. Torres sent another letter, received by me on January 28, notifying me of the non performance of the daily survey. I called him again, but this time he was not available to answer my call. I did not know at that time he had resigned to his position as RSO.

Since he did not answer my telephone call, I send a letter to him on February 9, 2002, requesting an urgent meeting. This meeting never took place. A time of great confusion and change came during the following weeks. Finally as you

Mr. Douglas Collins, Director  
Division of Material Safety  
Page 3

know, Mr. David Rhoe was appointed RSO and the radiation safety program was reinforced, reorganized and is under complete revision. By the end of March or April, 2002 I requested an official statement from the Chancellor or Licensee in relation to the daily survey issue. The licensee decision was to perform the daily surveys in the nuclear medicine area by the nuclear medicine personnel (nuclear medicine technologist). Since then, all the surveys are been performed daily in the clinical areas, in addition to the radiopharmaceutical preparation areas.

In my opinion, we performed all the surveys required by the license document in section 10.4 (B). Any changes in the license on specific procedures relating to the areas of byproduct material use, require an amendment and prior revision of the proposed change by the Radiation Safety Committee.

In addition, it is the RSO responsibility to take actions to correct the radiation safety issues, even if he has to take decisions on specific duties or responsibilities of personnel. If he is unable to correct the issue, the situation should go the RSC and from there to the higher University officials, the Chancellor or the Dean of Administration. Both University officials have the authority to implement administrative and decisional changes. To my knowledge, this issue was never brought to the RSC, Dean of Administration or the Chancellor. The RSO does not have the authority to change the license without the approval of the RSC or the licensee.

The nuclear medicine section of the University of Puerto Rico has been working with NRC license and requirement for more than 20 years. Throughout time the NRC inspector visits have identified only minor violations. On several occasions the results of the inspections were excellent. We have been proactive in implementing new rules, careful in the safe handling of materials, in the management of radiation sources, and in the management of radiation contaminations. My department has complied with the regulations and assignment given by the license and the RSO in an orderly manner. If major changes to procedures and to the license are done without the revision and approval of the RSC or without notifying the concerned personnel in a timely manner, it is difficult for me and my department to comply with the changes.

Mr. Douglas Collins, Director  
Division of Material Safety  
Page 4

Definitely the problem could have been solved on time with an effective communication and action from the RSO and/or his personnel with the RSC, the licensee and our personnel. Based on the above evidence one can conclude that all daily surveys require by our license under section 10.4(B) 17 were carried out properly and as required.

I ask for a reconsideration of your determination stated in the letter sent November 8, 2002.

Sincerely,

*Frieda Silva de Roldán*

Frieda Silva de Roldán, MD  
Nuclear Medicine Director  
Medical Sciences Campus, UPR

c. Mr Luis Reyes, Regional Administrator