UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Daniel Torres Ortiz, Consultant Mayagüez, Puerto Rico	)	IA 97-025
	)	

DEMAND FOR INFORMATION

I

In September 1990, Mr. Daniel Torres Ortiz performed radiological consulting activities for Dr. Luis A. Vázquez. Dr. Vázquez, now deceased, held License Nos. 52-16660-01, 52-16660-02, and 52-16660-03 initially issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30 on October 1, 1975. The license authorized Dr. Vázquez to possess and use a strontium-90 (Sr-90) source for the administration of brachytherapy radiation doses to the eye. The license was terminated on February 24, 1994. Subsequently, the possession and use of the source was transferred to Dr. José L. Fernández (Licensee) under an amendment to NRC License No. 52-25114-01 issued on January 14, 1994. Dr. Fernandez' license expired on February 28, 1996, but has not yet been terminated by the NRC.

II

On October 18, 1995, the NRC conducted a routine safety inspection of activities performed under the NRC license issued to Dr. Fernández. During this inspection, the inspector raised questions regarding the validity of the calibration of the Licensee's Sr-90 eye applicator (Serial Number 0204). Although the applicator was stamped with "Sr-90 100 mCi 7/76 Sn:0204," the original manufacturer's dose rate calibration certificate was missing. The

only documentation of source calibration available at the time of the inspection was the label attached to the source storage box which indicated a dose rate of 24 rads/sec and stated the method by which the dose rate was determined (i.e., using a low energy condenser R-chamber) and that it was performed by Mr. Torres. Since Sr-90 emits beta radiation and the dose rate from a beta radiation emitting source cannot be accurately measured with a low energy condenser R-chamber, the dose rate on the label was questionable.

In accordance with a Confirmatory Action Letter issued on October 19, 1996, Dr. Fernández initiated action to obtain a new source calibration. On January 25, 1996, the source manufacturer, DuPont Merck Pharmaceutical Company, determined that the Sr-90 source's true output was 53 ± 10 percent rads/sec. This dose rate (corrected for decay) equates to approximately 60 rads/sec in September 1990, not 24 rads/sec, as determined by Mr. Torres and used by Dr. Fernández in his opthamological treatment programs. The manufacturer certified traceability of the calibration to National Institute for Standards and Technology (NIST). As a result of the miscalibrated source, a significant number of Dr. Fernández' patients received brachytherapy misadministrations to the eye of more than two times the intended dose.

Upon further review of records, the NRC determined that in September 1990, Mr. Torres provided Sr-90 source output verification services for Dr. Luis A. Vázquez. In a September 15, 1990 letter (Attachment A) to Dr. Vázquez reporting the results of the source output verification of eye applicator (Serial Number 0204), Mr. Torres stated, in Spanish, "El rendimiento (Output) fué cotejado haciendo medidas con cámara R. de baja enegría. El mismo revela

una dosis de 24 Rads/Sec," which, when translated to English, states that the output of the Sr-90 eye applicator used by Dr. Vázquez was checked by making measurements with a low energy condenser R-Chamber and that the source output was determined to be 24 rads/sec.

As a result, on February 9, 1996, NRC contacted Mr. Torres by telephone regarding the services he performed in 1990 for Dr. Vázquez. The NRC followed up with a March 5, 1996, letter to Mr. Torres requesting certain documents pursuant to 10 CFR 21.21(d). On April 2, 1996, Mr. Torres responded to the March 5, 1996, request. In his letter, Mr. Torres stated that ". . . no calibration services were performed using instrumentation other than decay tables . . . used to calculate data based on output values available and given by the user." Mr. Torres further stated that "the Victoreen R-Chamber was used to spot check if the Strontium-90 [sic] 'Eye Applicator' was emitting radiation as requested by Dr. Luis Vázquez."

Mr. Torres' September 15, 1990 statement to Dr. Vázquez that the source output was based on a "measurement" and his April 2, 1996 letter to NRC stating that the output was determined by use of decay tables and output values available and given by the user and a spot check, are in conflict. In his September 15, 1990 letter to Dr. Vázquez, Mr. Torres did not clearly explain how he arrived at his stated output of 24 rads/sec. This is important because of the discrepancy between his stated output and the true dose rate at the time he determined the output. Therefore, further information is needed by the Commis to determine all the facts and circumstances of this case and whether information provided by Mr. Torres to the licensee on September 5,

1990 and to the Commission on April 2, 1996 was complete and accurate in all material respects, as required by 10 CFR 30.9. and whether submission of the April 2, 1996 letter was in violation of 10 CFR 30.10.

III

Accordingly, pursuant to sections 161c and 161o of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, the Commission needs the following information to determine whether enforcement or other action should be taken against you to ensure future compliance with NRC requirements:

A. Your letter to the NRC dated April 2, 1996, indicated that the output of the Sr-90 source was 24 rads/sec based on previous numbers available and in use. Please identify the previous numbers available and in use which formed the basis for your source output determination.

B. In your letter of April 2, 1996, to the NRC you stated that your letter of September 15, 1990, to Dr. Vázquez indicated that you had performed a "check" to verify radiation output. Describe why you believed your output measurement of 24 rads/sec with a Victoreen R-Chamber was accurate.

C. Who did you give your measurement results to in September 1990, and how did you explain their proper use?

D. Explain how a low energy Victoreen R-Chamber can be used for an absolute beta measurement of 24 rads/sec (i.e., how was your beta measurement of 24 rad/sec traceable to an NIST standard).

E. In the future, do you intend to use methods similar to those used for determining the output of Dr. Vázquez' eye applicator (i.e., using a low energy Victoreen R-Chamber)? If so, provide a technical basis for utilizing these methods.

F. How would you determine the output of a Sr-90 eye applicator, if you did not know the original surface dose rate?

G. How do you explain the conflicts between your April 2, 1996 letter to the NRC that you used a decay table to determine the output of the source and made a spot check with an R-Chamber measurement, and your September 15, 1990 letter to Dr. Vázquez in which you stated that the output was determined with a measurement using an R-Chamber?

H. Why should NRC have confidence that future consulting services performed by you for NRC licensees will be technically correct and properly documented?

You may provide any other information you would like the NRC to consider, including an assessment of whether the statements made in Section II of this Demand for Information are accurate. The information is to be submitted to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission,

Washington, D. C. 20555, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation.

You may respond to this Demand for Information by filing a written answer, under oath or affirmation, or by setting forth your reasons why this Demand for Information should not have been issued and, if the requested information is not being provided, the reasons why it is not being provided. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region II, Atlanta Federal Center, 61 Forsyth Street, S. W., Suite 23T85, Atlanta, Georgia 30303.

Upon review of your answer, or if no answer is filed, the Commission may institute a proceeding pursuant to 10 CFR 2.202 or take such other actions as may be necessary to ensure compliance with regulatory requirements. Your response to the Demand for Information will be considered before a decision is made in this matter. However, <u>if no answer is filed, we will proceed on the basis of available information</u>.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 25th day of April 1997

Attachment A: September 15, 1990 letter from Mr. Torres to Dr. Vazquez.