AVAX TECHNOLOGIES, INC.

Kamy A. Behzadi, Ph.D.
Executive Director of Operations & Head of Quality

Immunotherapies • Pharmaceuticals • Biotechnologies

MS16
P-8

January 8, 1999 *via fax/via Fed-Ex*

Docket No. 030-34903
Control No. 126375

Judith A Joustra
Senior Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuc ear Materials Safety
US Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Joustra,

This is in reference to your letter dated December 29, 1998 of your office and AVAX Technologies, Inc.'s application for a Nuclear Regulatory Commission license dated December 17, 1998.

1. As is mentioned in section 7 of AVAX's application, I will be the temporary Radiation Safety Officer (RSO) and the key point of contact during the review of our application and during the period of our license. I have completed training and have served as an RSO previously; however, I will obtain additional specific training for this instrumentation from Nordion. Furthermore, AVAX's Philadelphia Manufacturing Manager (under hiring) will be the new RSO and will complete training along with all other designated individuals. Training will be conducted by Nordion either at AVAX's facility located at 2000 Hamilton in Philadelphia or at the Canadian Irradiation Center in Quebec, Canada.

2. I confirm that the applicable regulation and conditions of AVAX's NRC license will be additional topics to be included in training materials.

3. I confirm that the room dedicated to the irradiators meet all structural requirements (such as weight, etc.); the area equipped by an access control system to ensure access by authorized individuals only. In addition, the room in which the irradiator will be located is equipped with a sprinkler system.

4. As mentioned in AVAX's application, equipment for contamination or radiation detection will be calibrated under AVAX's Standard Operating Procedure (under development). Any contamination or radiation detection device will be calibrated

4520 Main Street • Suite 930 • Kansas City, MO 64111 • Phone: (816) 960-1333 • Fax: (816) 960-1334

126375

at a frequency not exceeding a period of six months or conforming with the State authority requirements.

5. AVAX will establish an inventory and control system and document the receiving of shielded material. AVAX will monitor this in case of replacement, exchange or removal.

6. In order to monitor, document, and communicate radiation safety to personnel, AVAX will establish a control system for all manufacturing individuals. This system will require all manufacturing (restricted or nonrestricted) to wear a badge personal monitoring device. The film badge will be exchanged on monthly intervals. The exposed radiation dose will be documented in the employee's personnel file; in addition, the result will be communicated to the employee on a monthly basis.

7. AVAX's Emergency Procedures, which detailed specific instructions to our staff in case of emergency, is under development. The Manufacturing's Emergency Procedures which we submitted with our application will be used to assist us in development of these procedures.

8. I confirm that the leak tests will be performed at the interval approved by the NRC or Agreement State and specified in the Sealed Source and Device Registration Certificate.

9. I confirm that AVAX will implement and maintain procedures for routine maintenance of AVAX's irradiator and this procedure is in accordance with the manufacturer's written recommendations and instructions.

I would like to express my sincere gratitude for your prompt review and hope this written response satisfies all your questions for AVAX to receive an approval on its application.

If you have any further questions, please do not hesitate to call me at (816) 960-1333.

Sincerely,

Kamy A. Behzadi, Ph.D.
Exec. Dir. of Operations
Head of QA/QC