



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 16, 2006

Docket No. 03034903

License No. 37-30489-01

Henry Schea  
Director, Quality Systems  
AVAX Technologies, Inc.  
2000 Hamilton Street, Suite 200  
Philadelphia, PA 19103

SUBJECT: INSPECTION 03034903/2005001, AVAX TECHNOLOGIES, INC.,  
PHILADELPHIA, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Mr. Schea:

On September 19, 2005 and November 19, 2005, Craig Gordon of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Mr. Gordon discussed the findings of the inspection with you at the conclusion of the inspection and in followup phone calls.

As part of this inspection, we also reviewed the information in your January 25, 2006 letter relative to use of the irradiator and the status of the radiation safety officer (RSO). Your statement that the operation has been temporarily shutdown and that restart of the facility including use of the irradiator may begin in mid-2006 is understood. However, notification of NRC was required since no principal activities were conducted for a period of 24 months from the time of shutdown in 2003. The NRC is also concerned about radiation safety program oversight since the RSO named on the license has left the facility. We have received your letter dated January 23, 2006 requesting a license amendment to change the RSO, and this request is currently under review.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select

H. Schea  
AVAX Technologies, Inc.

2

**What We Do, Enforcement, then Enforcement Policy.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

***Original signed by John D. Kinneman***

John D. Kinneman, Chief  
Security and Industrial Branch  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

cc:  
Commonwealth of Pennsylvania

H. Schea  
AVAX Technologies, Inc.

3

Distribution:  
D. J. Holody, RI

DOCUMENT NAME: E:\Filenet\ML060480186.wpd

**SISP Review Complete: CGordon**

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	Cgordon/JDK f/		JDKinneman/JDK					
DATE	2/16/06		2/16/2006					

OFFICIAL RECORD COPY

## **NOTICE OF VIOLATION**

AVAX Technologies, Inc.  
Philadelphia, PA

Docket No. 03034903  
License No. 37-30489-01

During an NRC inspection conducted on September 19 and November 19, 2005, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 30.36(d)(3) requires that the licensee provide notification to the NRC in writing that no principal activities under the license have been conducted for a period of 24 months.

Contrary to the above, the licensee had not conducted principal activities under the license since 2002, but did not notify the NRC within 60 days that activities had ceased.

This is a Severity Level violation IV (Supplement IV).

- B. 10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, between January 1, 2001, and December 16, 2005, the licensee did not periodically review the radiation protection program content and implementation at least annually. Specifically, in calendar years 2001-2004 the annual review was not performed.

This is a Severity Level IV violation IV (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, AVAX Technologies, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington,

DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 16<sup>th</sup> day of February 2006