



# SCIENTIFIC ASSOCIATES, INC.

6200 S. LINDBERGH • ST. LOUIS, MO 63123 • TELEPHONE: (314) 487-6776 • FAX: (314) 487-8991

July 31, 1990

*License File*  
24-03548-01

Mr. Roy J. Caneano, Chief  
Nuclear Materials Safety  
Section 2  
United States Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, IL 60137

Dear Sir:

On June 7, 1990, Ms. E. R. Matson inspected our facility. Her comments and observations were appreciated and helpful.

The purpose of this letter is to respond to the Notice of Violation which we received as a result of the inspection.

On May 24, 1990, Scientific Associates decided to discontinue our NRC license. Letters dated June 1, 1990, to all of our clients who had previously sent radioactive samples informing them that no radioactive samples would be received. We expect to discontinue our license on or about November 1, 1990.

To assist your evaluation of our responses, we have restated each observation as it appears in the notice. Our comment which follows each observation is intended to address any issues contained in the observation.

Please do not hesitate to contact me if you have questions or additional information is required.

Sincerely,

SCIENTIFIC ASSOCIATES, INC.

*David W. Haywood*

David W. Haywood  
Radiation Safety Officer

DWH/bd

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# SCIENTIFIC ASSOCIATES, INC.

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## RESPONSE TO "NOTICE OF VIOLATION"

OBSERVATION 1. LICENSE CONDITION NO. 24 REQUIRES THAT LICENSED MATERIAL BE POSSESSED AND USED IN ACCORDANCE WITH THE STATEMENTS, REPRESENTATIONS, AND PROCEDURES CONTAINED IN CERTAIN REFERENCED DOCUMENTS.

THE REFERENCED LETTER DATED MARCH 26, 1986, STATES THAT IN AREAS WHERE RADIOACTIVE MATERIAL IS USED, WIPE TESTS WILL BE CONDUCTED QUARTERLY.

CONTRARY TO THE ABOVE, FROM APRIL 3, 1986, THROUGH FEBRUARY, 1990, THE LICENSEE FAILED TO CONDUCT WIPE TESTS IN AREAS WHERE RADIOACTIVE MATERIAL WAS USED.

THIS IS A SEVERITY LEVEL IV VIOLATION (SUPPLEMENT VI)

COMMENT: QUARTERLY WIPE TESTS WILL BE PERFORMED BY THE R.S.O. UNTIL THE LICENSE IS DISCONTINUED. THE EXPECTED DISCONTINUATION DATE IS ON OR ABOUT NOVEMBER 1, 1990.

OBSERVATION 2. LICENSE CONDITION NO. 24 REQUIRES THAT LICENSED MATERIAL BE POSSESSED AND USED IN ACCORDANCE WITH THE STATEMENTS, REPRESENTATIONS, AND PROCEDURES CONTAINED IN CERTAIN REFERENCED DOCUMENTS.

THE REFERENCED LETTER DATED MARCH 26, 1986, STATES THAT THE RADIATION SAFETY OFFICER (RSO) WILL PERFORM INDEPENDENT SURVEYS AT THREE MONTH INTERVALS.

CONTRARY TO THE ABOVE, FROM APRIL 3, 1986, THROUGH JUNE 7, 1990, THE RSO FAILED TO PERFORM INDEPENDENT SURVEYS.

THIS IS A SEVERITY LEVEL IV VIOLATION (SUPPLEMENT VI)

COMMENT: THE RADIATION SAFETY OFFICER WILL PERFORM INDEPENDENT SURVEYS OF THE LABS AND STORAGE AREAS ON A QUARTERLY BASIS UNTIL THE LICENSE IS DISCONTINUED.

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RESPONSE TO "NOTICE OF VIOLATION" (CONTINUED)

OBSERVATION 3. LICENSE CONDITION NO. 24 REQUIRES THAT LICENSED MATERIAL BE POSSESSED AND USED IN ACCORDANCE WITH THE STATEMENTS, REPRESENTATIONS, AND PROCEDURES CONTAINED IN CERTAIN REFERENCED DOCUMENTS.

THE REFERENCED LETTER DATED MARCH 26, 1986, STATES IN ITEM 1.c., THAT THE CRITERIA AND FREQUENCIES FOR BIOASSAYS FOR PERSONNEL USING IODINE-125 DESCRIBED IN REGULATORY GUIDE 8.20 WILL BE FOLLOWED. REGULATORY GUIDE 8.20 STATES WHEN QUANTITIES OF IODINE-125 HANDLED IN UNSEALED FORM ARE GREATER THAN 10% OF 10 MILLICURIES, ROUTINE BIOASSAYS MAY STILL BE NECESSARY UNDER CERTAIN CIRCUMSTANCES. A WRITTEN JUSTIFICATION FOR NOT PERFORMING SUCH MEASUREMENTS SHOULD BE PREPARED AND RECORDED FOR SUBSEQUENT REVIEW DURING NRC INSPECTIONS WHENEVER A BIOASSAY IS NOT PERFORMED AND THE QUANTITIES HANDLED EXCEED 10% OF 10 MILLICURIES.

CONTRARY TO THE ABOVE, FROM APRIL 1986 THROUGH FEBRUARY 1990, THE LICENSEE ROUTINELY RECEIVED 1.6 MILLICURIES OF UNSEALED IODINE-125 ONCE EVERY TWO WEEKS (QUANTITIES GREATER THAN 10% OF 10 MILLICURIES), AND FAILED TO PERFORM ANY BIOASSAYS, AND FAILED TO PREPARE AND RECORD A WRITTEN JUSTIFICATION FOR NOT PERFORMING SUCH MEASUREMENTS.

THIS IS A SEVERITY LEVEL IV VIOLATION (SUPPLEMENT VI)

COMMENT: SCIENTIFIC ASSOCIATES RECEIVED 1.6 MILLICURIES OF UNSEALED IODINE-125 EVERY THREE WEEKS. IT ARRIVED DIVIDED INTO 9 CONTAINERS. THREE TESTS WERE PERFORMED ON THE PRODUCT. THEY WERE:

<u>TEST</u>	<u># OF VIALS REQUIRED</u>
SAFETY	3
PYROGEN	4½
BLOOD CLEARANCE	1½



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RESPONSE TO "NOTICE OF VIOLATION" (CONTINUED)

NO ANALYST HANDLED MORE THAN 5 VIALS AT ANY ONE TIME. THIS IS EQUIVALENT TO APPROXIMATELY 0.9 MILLICURIES OF IODINE-125. WE DID NOT THINK THAT AT THIS LEVEL WE WERE REQUIRED TO PERFORM THE BIOASSAY.

THE LAST SAMPLE OF IODINE-125 WAS RECEIVED ON MARCH 22ND, 1990. THE CLIENT DISCONTINUED THE PROJECT AND SENT NO MORE AFTER THAT DATE.