



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

December 24, 2006

Docket No. 03037208

License No. 45-31125-02MD

Allen C. Jones, R.Ph.  
Radiation Safety Officer/Facility Manager  
Radiology Services of Northern Virginia  
13870 Park Center Drive  
Building #5, Bay #22  
Herndon, VA 20171-3216

SUBJECT: INSPECTION 03037208/2006001, RADIOLOGY SERVICES OF NORTHERN VIRGINIA, HERNDON, VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Mr. Jones:

On August 1, 2006, Steven Courtemanche of this office observed Radiology Services of Northern Virginia transportation activities at one of your client sites. Mr. Courtemanche's findings were discussed with you during a telephone call on August 1, 2006. On September 19, 2006, Mr. Courtemanche completed the safety inspection at your Herndon address of activities authorized by your 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. Additional information provided in your correspondence received September 25, 26 and 29, 2006, was also examined as part of the inspection. The findings of the inspections were discussed with you on September 19, 2006, and with Robert Beightol of your staff on December 22, 2006. The enclosed report presents the results of this inspection.

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, Academic, and Industrial 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 **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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

A. Jones  
Radiology Services of Northern Virginia

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Your cooperation with us is appreciated.

Sincerely,

***Original signed by James P. Dwyer***

James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:

1. Inspection Report No. 03037208/2006001
2. Notice of Violation

cc:  
Commonwealth of Virginia

A. Jones  
Radiology Services of Northern Virginia

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**SUNSI Review Complete: SCourtemanche**

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NAME	Scourtemanche/jpd f/		JDwyer/jpd				
DATE	12/22/2006		12/24/2006				

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## NOTICE OF VIOLATION

Radiology Services of Northern Virginia  
Herndon, VA

Docket No. 03037208  
License No. 45-31125-02MD

During an NRC inspection conducted on August 1, and September 19, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of September 19, 2006, individuals who were working in the radiopharmaceutical preparation and distribution areas, restricted areas, had not been adequately instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and the conditions of the license. Specifically, (1) observations of a pharmacy technician by the inspector noted that the technician was holding a syringe shield inappropriately while filling an order for a radiopharmaceutical, causing unintended radiation exposure to the technician's hands; (2) a review of documents concerning the performance of radiological surveys for radiation dose rate levels and contamination revealed an inadequate knowledge of the use of counting and survey equipment by at least one technician; and (3) interviews of personnel involved in the transportation of radiopharmaceuticals by the inspector revealed an inadequate knowledge of emergency procedures to be followed in case of an accident while transporting radiopharmaceuticals.

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

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (a) within his immediate reach while he is restrained by the lap belt; and (b) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (a) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle.

Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on August 1, 2006, the licensee transported technetium-99m, a licensed material, outside the site of usage, as specified on the NRC license, or on a public highway, and the driver of the vehicle did not ensure that the shipping papers were readily available in the driver's compartment, as required. Specifically, between July 2006 and August 1, 2006, the shipping papers were affixed to the shipments in the cargo carrying area of the vehicle and not within the immediate reach of the driver and readily visible to a person entering the driver's compartment or in a holder mounted to the door. Also, on September 19, 2006, drivers indicated they often took the clipboard containing the shipping papers with them when they left the vehicle to make a delivery.

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

Pursuant to the provisions of 10 CFR 2.201, Radiology Services of Northern Virginia 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 24 day of December 2006

U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No. 03037208/2006001  
Docket No. 03037208  
License No. 45-31125-02MD  
Licensee: Radiology Services of Northern Virginia  
Location: 13870 Park Center Drive  
Building #5, Bay #22  
Herndon, Virginia 20171-3216  
Inspection Dates: August 1 and September 19, 2006  
Date Followup  
Information Received: September 25, 26 and 29, and December 22, 2006

Inspector:	<b><i>Original signed by: James P. Dwyer</i></b>	<b><i>December 24, 2006</i></b>
	_____ Steven Courtemanche Health Physicist	_____ date
Approved By:	<b><i>Original signed by James P. Dwyer</i></b>	<b><i>December 24, 2006</i></b>
	_____ James P. Dwyer, Chief Commercial and R&D Branch Division of Nuclear Materials Safety	_____ date

## **EXECUTIVE SUMMARY**

Radiology Services of Northern Virginia  
NRC Inspection Report No. 03037208/2006001

On August 1, 2006, during the inspection of a Radiology Services of Northern Virginia (RSNOVA) client, the inspector reviewed RSNOVA's transportation of licensed radioactive materials.

On September 19, 2006, an announced safety inspection was performed of activities authorized by the RSNOVA limited scope license at its Herndon, Virginia facility. The inspection consisted of: (1) organization and scope of the program; (2) management oversight of the program; (3) facilities and equipment; (4) material receipt and use; (5) training of workers; (6) radiation surveys; (7) radiation protection; (8) waste; (9) posting and labeling; and (10) transportation. Additional information provided in licensee correspondence received September 25, 26 and 29, 2006, was also examined as part of the inspection. Within the scope of this inspection, two apparent violations were identified: (1) failure to adequately instruct personnel working in the radiopharmaceutical preparation and distribution areas, restricted areas, in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the regulations and the conditions of the license as required by 10 CFR 19.12; and (2) failure of the driver of a motor vehicle containing hazardous material to ensure that the shipping papers were readily available to, and recognizable by, authorities in the event of accident or inspection as required by 49 CFR 177.817(e).

## REPORT DETAILS

### **I. Organization and Scope of the Program**

a. Inspection Scope

The inspector interviewed the licensee's staff, toured facilities, examined equipment and reviewed records of the licensee's activities.

b. Observations and Findings

The licensee is authorized to: prepare and distribute radioactive drugs and molybdenum-99/technetium-99m generators for medical and non-medical use; redistribute sealed sources for medical and non-medical use; and redistribute prepackaged kits in accordance with 10 CFR 31.11. The licensee is also authorized to possess materials for calibration and checking of the licensee's instruments and depleted uranium for shielding of molybdenum-99/technetium-99m generators. The NRC license was issued on May 23, 2006, and licensed operations began shortly thereafter. The radiopharmacy is open seven days a week beginning at about 1:30a.m. Iodine-131 capsules are received from a manufacturer and are compounded on site during the second (day) shift. The licensee has not distributed any yttrium-90 or any licensed material covered by 10 CFR 35.400, 35.500, or 31.11. The licensee employs three full-time and one part-time radiopharmacist, three pharmacy technicians, a dispatcher and eight drivers.

c. Conclusions

No violations or safety concerns were identified.

### **II. Management Oversight of the Program**

a. Inspection Scope

The inspector interviewed the individual who serves as the Facility Manager/Radiation Safety Officer (RSO)/radiopharmacist, regarding his knowledge of the radiation safety program and his activities with regard to maintaining the program.

b. Observations and Findings

Radiology Services of Northern Virginia (RSNOVA) corporate management is affiliated with another NRC license, Radiology Services of Hampton Roads. Corporate management of both facilities is located off-site. The Facility Manager/RSO had a good knowledge of the regulations and the license commitments; however, observations by the inspector and a review of records indicated that the Facility Manager/RSO's oversight of the day-to-day activities could be improved. On the day of the inspection, the inspector: (1) observed a pharmacy technician handling syringes containing radioactive materials in a manner that resulted in unnecessary exposure of the

technician's fingers (see Section V of this report); (2) noted that records of daily radiation surveys indicated a lack of understanding by the technician staff on the use of survey and counting instrumentation (see Section VI of this report); and (3) determined through interviews of drivers that, as of September 19, 2006, some were not keeping the shipping papers stored appropriately in their vehicles (see Section X of this report).

The licensee pays for the services of a consulting health physicist who performs an audit of the facility on a monthly basis.

c. Conclusions

The inspector concluded that the Facility Manager/RSO's oversight of the licensed program could be improved.

### **III. Facilities and Equipment**

a. Inspection Scope

The inspector toured the Herndon facility and questioned personnel regarding the use of specific facilities and equipment.

b. Observations and Findings

The licensee's facilities are located in an industrial park and consist of administrative offices, a radiopharmaceutical preparation area and distribution area. The doors to the areas of use are locked to prevent entry by unauthorized personnel. The areas of use consist of six rooms: a blood labeling area with a laminar-flow hood; a generator storage area with an iodine-131 compounding station; a radiopharmaceutical dispensing laboratory with two hoods and a quality control area; a packaging area; a waste storage and "breakdown" area; and a general storage area. There are hand/foot monitors present at each exit from the area of use. The licensee possesses a sufficient number of radiation survey and radiation detection instruments that are operable and calibrated. Lead syringe shields and carrying devices were in evidence and used appropriately with one exception noted in Section V of this report.

c. Conclusions

No violations or safety concerns were identified.

### **IV. Material Receipt, Use, Transfer, and Control**

a. Inspection Scope

The inspector interviewed the RSO regarding material receipt, use, transfer, and control and reviewed applicable records.

b. Observations and Findings

The licensee receives two generators on Monday, two on Tuesday, and one on Thursday of each week which are delivered by a common carrier. Three hundred doses are prepared for shipment to clients each day. There are a total of twenty clients. As needed, the licensee receives iodine-131 as capsules or liquid for compounding and distribution to licensees. The inspector observed the licensee's procedure for preparing packages for shipment to clients including: surveys for radiation dose rate levels, surface contamination, and labeling.

c. Conclusions

No violations or safety concerns were identified.

## **V. Training of Workers**

a. Inspection Scope

The inspector reviewed documentation of the licensee's training program, observed individuals performing licensed activities, interviewed individuals regarding the training they received, and reviewed training records.

b. Observations and Findings

The inspector noted that the licensee's training program was extensive and concluded that, if implemented as designed, it would cover all of the necessary information that personnel would need to perform their job safely. A review of the training records indicated that all personnel employed by the licensee and who handle radioactive material had received the training required of occupationally exposed individuals.

10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses. However, on September 19, 2006, the inspector noted that individuals who were working in the radiopharmaceutical preparation and distribution areas, restricted areas, had not been adequately instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the regulations and the conditions of the license. Specifically, (1) observations of a pharmacy technician identified that he was steadying the syringe containing radioactive material by holding the unshielded needle end with one hand and holding the shielded end of the syringe with the second hand, resulting in unnecessary radiation exposure of the hand; (2) a review of the licensee's radiological survey records revealed that all personnel involved in radiation dose rate and contamination surveys may not have understood how to use the equipment (see Section VI of this report); and (3) interviews of the drivers determined that some did not have a good understanding of the licensee's emergency procedures in case of an accident or

where to keep shipping papers when the driver was not in the car (see Section X of this report).

This is an apparent violation of 10 CFR 19.12.

c. Conclusions

An apparent violation of 10 CFR 19.12 was identified. While the training was provided, the training was inadequate in that the individuals did not exhibit an understanding or comprehension of the materials covered.

## **VI. Radiation Surveys**

a. Inspection Scope

The inspector interviewed available staff, the RSO and the Health Physics Consultant regarding surveys performed, and reviewed survey records.

b. Observations and Findings

The RSO indicated that surveys for contamination and radiation dose rate levels were performed by personnel on the day shift and both handwritten and computer records were maintained. The health physics consultant informed the inspector that during his audits of the program, he was unaware of the handwritten records and only reviewed the computerized records. The inspector's review of the computer and handwritten records determined that there was a discrepancy in how data was recorded. Specifically, on some weeks, records of the survey meter operability check indicates a source reading of 0.02 millirem per hour (mR/hr) for all the survey meters when calibration records indicate the check source, depending on the meter, should give a reading of 1.2 to 1.5 mR/hr. Also, the inspector noted the background reading for survey meters is documented in the handwritten records for the period of July 17-20, 2006, as 1010 millirem per hour while the computer records for the same period, performed by a different individual, indicate more accurately that background is between 0 and 0.03 mR/hr. Of note, the computer records for July 24 -27 and 31, 2006, have background readings for the survey instrument of greater than 1000 mR/hr and these readings correspond to measurements made on the same days with the instrument used to measure removable contamination. The inspector concluded that accurate surveys were performed by other individuals during the times in question. Surveys performed by the inspector identified only limited contamination in areas where contamination would be expected such as in dispensing hoods.

c. Conclusions

This finding regarding radiation surveys is being cited as an apparent training violation in Section V.

## **VII. Radiation Protection**

### a. Inspection Scope

The inspector observed personnel wearing dosimetry, interviewed personnel and reviewed dosimetry records.

### b. Observations and Findings

The inspector observed that all personnel were wearing appropriate dosimetry. All personnel interviewed indicated that they received personnel dosimetry on a monthly basis and turned in the previous month's dosimetry at that time. The inspector's review of the exposure records did not identify any cases where personnel dosimetry was not assigned or returned in a timely manner. Interviews of the RSO determined that the licensee possessed one pencil dosimeter to assign to visitors. On those occasions when a group toured the facility, the single dosimeter was assigned to one individual and the group was assigned that individual's dose. The RSO related one instance when the dosimeter was not assigned and stated that it was because the licensee had ceased operations for the day and all sources were in a shielded condition.

### c. Conclusions

No violations or safety concerns were identified.

## **VIII. Radioactive Waste Management**

### a. Inspection Scope

The inspector interviewed licensee personnel regarding the licensee's methods for disposal of licensed material.

### b. Observations and Findings

Licensed material with a half-life of less than 120 days is disposed of through decay-in-storage. Sealed sources are sent back to the manufacturer for disposal. Radioactive waste received back from the licensee is segregated according to half-life and decayed. Appropriate surveys were made of licensed material kept as waste to determine that radiation dose rate levels did not exceed background prior to disposal as non-radioactive waste.

### c. Conclusions

No violations or safety concerns were identified.

## **IX. Posting and Labeling**

### a. Inspection Scope

The inspector observed required postings and labeling during a tour of the facility.

### b. Observations and Findings

A tour of the areas of use and the lunchroom of the facility by the inspector determined that all required postings and labeling were present.

### c. Conclusions

No violations or safety concerns were identified.

## **X. Transportation**

### a. Inspection Scope

On August 1, 2006, during the inspection of a RSNOVA client facility, the inspector interviewed the RSNOVA driver, reviewed his paperwork, and observed how radioactive material packages were transported. During the September 19, 2006, inspection of RSNOVA, the inspector interviewed personnel involved in the shipments of radiopharmaceuticals and observed the manner in which packages were transported.

### b. Observations and Findings

On August 1, 2006, the inspector interviewed a driver who was delivering radiopharmaceuticals to a client. It was observed that the shipping papers of each client were attached to the client's package in the rear of the vehicle instead of being kept on the driver's seat or in a folder on the door in the driver's absence. The driver indicated to the inspector that the licensee followed the above procedure for all deliveries. The RSO was notified of the apparent violation by telephone and he informed the inspector that appropriate actions would be taken to correct the violation.

On September 19, 2006, the inspector interviewed other drivers and determined that the shipping papers were no longer attached to the packages but instead were kept on a clipboard with the driver in the cab of the vehicle. The inspector noted that this met the regulatory requirement; however, drivers stated that they sometimes would take the clipboard with them when making a delivery into a building, leaving no copies of the shipping papers in the vehicle for the other packages.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (a) within his immediate reach while he is restrained by the lap belt; and (b) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (a) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle.

This is an apparent violation of 49 CFR 177.817(e).

Other aspects of the transportation of licensed material, such as blocking, bracing and labeling, were conducted in accordance with the regulations and the commitments in the license made by the licensee.

c. Conclusions

One apparent violation of 49 CFR 177.817(e) was identified.

## **XI. Exit Meeting**

The inspector performed an exit meeting with the Radiation Safety Officer on September 19, 2006. The inspector reviewed the inspection and discussed the apparent violations and the concern. Following the inspection, the NRC Office of Investigations reviewed the failure of the pharmacy technician to properly perform and document surveys, as described in Section VI of this report. The inspector contacted the licensee on December 22, 2006, and provided the final results of the inspection.

## PARTIAL LIST OF PERSONS CONTACTED

### Licensee

\* Allen C. Jones, R.Ph., Facility Manager/Radiation Safety Officer  
Syed Jeffrey, Pharmacy Technician  
Brian King, Dispatcher  
Joseph Brown, Driver  
Kevin Brooks, Driver  
Ronald Fields, Pharmacy Technician  
Michael Lairmore, Health Physics Consultant  
\*\* Robert Beightol, R. Ph.

\* Attended Exit Meeting on September 19, 2006  
\*\* Attended Exit Meeting on December 22, 2006