

September 21, 2011

EA-11-179

Saad Mossallati, M.D.  
Owner/Medical Director  
Associated Specialists, Inc.  
200 Rt. 98 West, Suite 107 Medwood Plaza  
Nutter Fort, WV 26301

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report No. 03037941/2011001 and  
Office of Investigations Report No. 1-2011-004

Dear Dr. Mossallati:

This refers to the inspection conducted on April 19, 2011, at the Associated Specialists, Inc. (ASI) facility in Bridgeport, West Virginia. Additional information, contained in correspondence from ASI on May 2, 10, 30, and 31, 2011, and June 13 and 28, 2011, was also reviewed as a part of this inspection. This inspection examined activities conducted under your license as they relate to safety and compliance with the NRC's rules and regulations and with the conditions in your license, associated with the use of licensed materials within ASI's nuclear medicine department and mobile nuclear device operations. The results of the inspection, including identification of several apparent violations, were discussed with you and other members of your organization during a telephonic exit meeting on August 16, 2011. The apparent violations were also documented in an inspection report, issued on August 26, 2011.

In addition to the inspection, an investigation was conducted by the NRC Office of Investigations (OI), which was completed on March 8, 2011. The purpose of the investigation was to determine if ASI willfully violated its license conditions by operating without a Radiation Safety Officer (RSO) or authorized user (AU). Based on the results of that investigation, the NRC did not identify any wrongdoing.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations, before we made our enforcement decision, by either attending a predecisional enforcement conference or by providing a written response. On August 30, 2011, Mr. Marc Ferdas spoke with you; and you indicated that a written response to the inspection report or a predecisional enforcement conference would not be necessary.

Therefore, based on the information developed during the inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The most significant violations involve ASI failing to: (1) limit operation with a temporary RSO to a period of 60 days, in accordance with 10 CFR 35.24(c); and (2) ensure that its AU provided adequate supervision to licensee staff who were involved in the receipt, possession, use, transfer or preparation of byproduct material, in accordance with 10 CFR 35.27.

Specifically, after the RSO left the company on June 8, 2010, a temporary RSO was assigned for more than 180 days. As a result, ASI lacked the critical oversight needed to ensure compliance with NRC regulations, and that staff were properly trained in radiation safety practices and regulatory requirements. The RSO and AU provide a critical role of ensuring that medical program activities are being conducted safely and in accordance with NRC regulations. Because the two violations are related, the NRC has characterized them collectively as one Severity Level (SL) III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III problem. Because your facility has not been the subject of escalated enforcement actions within the last two years, or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has determined that credit for corrective actions is warranted. The actions taken by ASI in response to receiving a Confirmatory Action Letter from the NRC on October 14, 2010, were considered, in addition to the actions taken by ASI to address all of the inspector's observations during their onsite inspection in April 2011. These actions included: (1) submitting a license amendment (which was approved by the NRC) for a new, permanent RSO, on October 21, 2010; (2) conducting a training session with the AU, the owner of the practice, and the nuclear medicine technologist, on May 30, 2011, to review revised policies and procedures and review responsibilities; and, (3) updating ASI's Emergency Contact list to ensure the staff was aware of, and able to contact the applicable individuals if needed.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III problem constitutes an escalated enforcement action that may subject you to increased inspection effort.

In addition to the SL III problem, seven SL IV violations are also documented in the attached Notice of Violation (Notice). These violations are being cited because they were identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations, (2) the actions planned or already taken to correct the violations and prevent recurrence, and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03037941/2011001 and in this letter. Therefore, you are not required to respond to this letter unless the description in these two documents does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if you choose to provide one) will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

*/RA/*

William M. Dean  
Regional Administrator

Docket No. 030-37941  
License No. 47-31344-02

Enclosure: Notice of Violation

cc: State of West Virginia  
Mark Perna, Radiation Safety Officer

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if you choose to provide one) will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at [\(http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/\)](http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

William M. Dean  
Regional Administrator

Docket No. 030-37941  
License No. 47-31344-02

Enclosure: Notice of Violation

cc: State of West Virginia  
Mark Perna, Radiation Safety Officer

**Distribution: see next page**

**SUNSI Review Complete: AED (Reviewer's Initials)**

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## NOTICE OF VIOLATION

Associated Specialists, Inc. (ASI)  
Bridgeport, West Virginia

Docket No. 030-37941  
License No. 47-31344-02  
EA-11-179

During an NRC inspection conducted on April 19, 2011, involving in-office review of additional information (contained in correspondence from ASI dated May 2, 10, 30, and 31, 2011, and June 13 and 28, 2011), for which a telephonic exit meeting was conducted on August 16, 2011, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- I. 10 CFR 35.24(c) allows, in part, that for up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer.

Contrary to the above, ASI permitted an authorized user to function as a temporary Radiation Safety Officer for a period greater than 60 days. Specifically, after ASI's Radiation Safety Officer left the company on June 8, 2010, the authorized user functioned as the temporary Radiation Safety Officer until October 13, 2010, a period greater than 60 days.

- II. 10 CFR 35.27 requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by 35.11(b)(1), shall instruct the supervised individual in the licensee's written radiation protection procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, from August 16, 2009 until April 19, 2011, ASI did not instruct supervised individuals in the licensee's written radiation protection procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. Specifically, the authorized user had limited oversight of the program, such that ASI personnel under the supervision of the authorized user had not spoken to the authorized user and had not received instructions associated with ASI's written radiation protection procedures, NRC regulations, ASI's license conditions, and the requirement that supervised individuals follow the instructions of the supervising authorized user for medical uses of byproduct material.

Violations I and II constitute a Severity Level III problem (Section 6.3).

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

Contrary to the above, ASI did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, ASI did not perform an audit of their radiation safety program for calendar year 2009, and the 2010 audit only included a review of activities conducted from August to December of 2010.

This is a Severity Level IV violation (Section 6.3).

- IV. 10 CFR 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, on numerous occasions between August 25, 2010 and April 19, 2011, ASI used dosages that did not fall within the prescribed dosage range or if the dosage differed from the prescribed dosage by more than 20 percent without being directed by the authorized user. Specifically, the authorized user prescribed dosages for Technetium-99m of 40 mCi and 13 mCi for stress and rest fractions; however, during the Technetium-99m shortage, dosages of 30 mCi and 10 mCi were received and administered. The administered dosages to the patients differed from the prescribed dosages by 25% and 23%, without approval from the authorized user.

This is a Severity Level IV violation (Section 6.3).

- V. 10 CFR 35.60(b) requires that a licensee calibrate the instrumentation required in paragraph (a) of this section (dose calibrator) in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, as of April 19, 2011, ASI did not calibrate a dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, ASI did not perform accuracy, geometry and linearity testing prior to using the dose calibrator on April 11, 2011, after moving to their new facility.

This is a Severity Level IV violation (Section 6.3).

- VI. License Condition 15 of NRC license 47-31344-02 requires that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents, including enclosures, dated October 28, 2008, January 14, 2009, and January 16, 2009. In correspondence dated October 28, 2008, January 14, 2009, and January 16, 2009, ASI committed to have procedures for survey meter calibrations, area surveys, and mobile emergency response procedures.

Contrary to the above, as of April 19, 2011, ASI did not have procedures they committed to develop and maintain per Condition 15 of their NRC license (47-31344-02). Specifically, ASI did not have written procedure for survey meter calibrations, area surveys, and mobile emergency response.

This is a Severity Level IV violation (Section 6.3).

- VII. 10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the site of usage, as specified in their NRC license, or where transport is on public highways, 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)(2)(i) requires that when a driver is at the vehicle's controls, the shipping paper shall be within his immediate reach while he is restrained by the lap belt; and 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.

Contrary to the above, as of April 19, 2011, ASI did not store their shipping paper within the immediate reach of the driver while he is restrained by the lap belt; and 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. Specifically, shipping papers were stored on the outside of the Type A container which was kept in the back of ASI's mobile van.

This is a Severity Level IV violation (Section 6.8).

- VIII. 10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the site of usage, as specified in their NRC license, or where transport is on public highways, 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 172.704(c)(1)(ii) requires, in part, that a new HAZMAT employee, or a HAZMAT employee who changes job functions may perform those functions prior to the completion of training provided that the employee performs those functions under the direct supervision of a properly trained and knowledgeable hazmat employee; and the training is completed within 90 days after employment or a change in job function.

Contrary to the above, ASI did not provide a new HAZMAT employee initial HAZMAT training within 90 days after employment or a change in job function. Specifically, the nuclear medicine technologist started their employment with ASI on August 16, 2010, and did not receive HAZMAT training until January 3, 2011.

This is a Severity Level IV violation (Section 6.3).

- IX. 10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the site of usage, as specified in their NRC license, or where transport is on public highways, 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 172.203(d) requires, in part, that a licensee list the description for a shipment of a Class 7 (radioactive) material which includes the following additional entries as appropriate: the name of each radionuclide in the Class 7 (radioactive) material, a description of the physical and chemical form of the material, the activity contained in each package of the shipment, and the category of label applied to each package.

Contrary to the above, prior to April 19, 2011, ASI did not list the description for a shipment of a Class 7 (radioactive) material, which included the following additional entries as appropriate: the name of each radionuclide in the Class 7 (radioactive) material, a description of the physical and chemical form of the material, the activity contained in each package of the shipment, and the category of label applied to each package. Specifically, ASI did not list all nuclear material being transported in their mobile van on their shipping papers. A Cobalt-57 flood source was not listed on ASI's shipping papers.

This is a Severity Level IV violation (Section 6.8).

The NRC has concluded that information regarding: (1) the reason for the violations, (2) the actions planned or already taken to correct the violations and prevent recurrence, and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03037941/2011001, and in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description in those two documents does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-11-179," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, at 475 Allendale Rd., King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 21<sup>st</sup> day of September 2011