U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03037941/2011001
Docket No.	03037941
License No.	47-31344-02
Licensee:	Associated Specialists, Inc.
Location:	527 Medical Park Drive, Suite 204, Bridgeport, WV
Inspection Dates:	April 19, 2011; Telephonic debrief on May 3, 2011; Telephonic exit on August 16, 2011
Follow-up Information Dated:	May 2, May 10, May 30, May 31, June 13, and June 28, 2011

Inspector: ***/RA M. S. Ferdas for/*** ***08/18/11***

Janice Nguyen — date
Health Physicist
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EXECUTIVE SUMMARY

Associated Specialists, Inc.
NRC Inspection Report No. 03037941/2011001

A special, unannounced inspection was conducted at Associated Specialists, Inc. (ASI) in Bridgeport, West Virginia on April 19, 2011. 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 part of this inspection. The inspection was performed in accordance with NRC Inspection Procedure 87131 and reviewed activities associated with the use of licensed materials within ASI's nuclear medicine department and mobile nuclear medicine operations. The inspector conducted interviews with ASI personnel, observed day-to-day operations and equipment testing, toured ASI's facilities, and reviewed documents and procedures.

Based on the results of this inspection, nine apparent violations of NRC requirements were identified. Specifically,

- ASI permitted an authorized user (AU) to function as a temporary Radiation Safety Officer (RSO) for greater than 60 days, which was not in accordance with 10 CFR 35.24(c). Specifically, after ASI's RSO left the company on June 8, 2010, the AU functioned as the temporary RSO until October 13, 2010. The NRC issued a Confirmatory Action Letter (CAL) on October 14, 2010, which suspended operations until a license amendment was issued with a new RSO established.

- ASI did not ensure that adequate supervision was provided to individuals under the supervision of the AU, as required by 10 CFR 35.27. Specifically, the AU had moved out of state in July 2009 and as a result had limited oversight of the program. From August 16, 2010 to April 19, 2011, new ASI personnel under the supervision of the AU had not spoken to the AU 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 AU for medical uses of byproduct material.

- ASI did not periodically (at least annually) review the radiation protection program content and implementation, as required by 10 CFR 20.1101(c). Specifically, ASI did not perform an audit of their radiation safety program for calendar year 2009 and the 2010 audit was limited and only included a review of activities conducted during the fourth quarter of 2010.

- ASI administered dosages that differed from the prescribed dosage by more than 20% without being directed by the AU, as required by 10 CFR 35.63(d). Specifically, the AU prescribed dosages for Technetium-99m (Tc-99m) of 40 mCi and 13 mCi for stress and rest fractions; however, during the Tc-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 AU.

- ASI did not calibrate a dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions, as required by 10 CFR 35.60(b). Specifically, ASI did not perform accuracy, geometry and linearity testing after moving and prior to using the dose calibrator on April 11, 2011, at their new facility.

- ASI did not have the procedures they committed to develop and maintain per Condition 15 of their NRC license (47-31344-02). Specifically, 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. As of April 19, 2011, ASI had not developed these procedures.

- ASI did not properly store shipping papers within their mobile van when they were transporting radioactive material as required by 49 CFR 177.817(e)(2)(i). Specifically, shipping papers were not within the driver's immediate reach and were not readily visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the driver's side of the vehicle. The shipping papers were stored on the outside of the Type A container which was kept in the back of ASI's mobile van.

- ASI did not provide training to personnel associated with their mobile nuclear medicine operations, as required by 49 CFR 172.704(c)(1)(ii). Specifically, ASI did not provide HAZMAT training within 90 days of when an ASI employee started employment as a mobile nuclear medicine technologist (NMT). The NMT started their employment with ASI on August 16, 2010, and did not receive HAZMAT training until January 3, 2011.

- ASI did not list all nuclear material being transported in their mobile van on their shipping papers, as required by 49 CFR 172.203(d). Specifically, a Cobalt-57 flood source was not listed on ASI's shipping papers.

REPORT DETAILS

a. Inspection Scope

A special, unannounced inspection was conducted at Associated Specialists, Inc. (ASI) in Bridgeport, West Virginia on April 19, 2011. Additional information, contained in correspondence from ASI on May 2, 24, and 31, 2011 and June 13 and 28, 2011, was also reviewed as part of this inspection. The inspection was performed in accordance with NRC Inspection Procedure 87131. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight.

The inspector assessed ASI's performance associated with the use of licensed materials within their nuclear medicine and mobile nuclear medicine operations. The inspection also included a review of ASI's management of the radiation safety program, including oversight of activities by the Radiation Safety Officer (RSO), authorized user (AU), and senior management.

The inspector conducted interviews with ASI personnel, observed day-to-day operations and equipment testing, toured ASI's facilities, and reviewed documents and procedures.

b. Observations and Findings

ASI's medical license (License Number 47-31344-02) authorizes ASI to conduct fixed and mobile nuclear medicine studies authorized by 10 CFR 35.200. The license was issued in February 2009. The licensee has five mobile client license agreements in place, but currently only services the base location and one location in Buckhannon, West Virginia. ASI performs nuclear medicine diagnostic tests consisting of rest and stress cardiac perfusion studies.

Management Oversight of the Program

Between February 2009 and June 2010, ASI's nuclear medicine technologist also functioned as the RSO. On June 8, 2010, the RSO informed the NRC in an email that they had ended their employment with ASI and wanted to be removed as the RSO on ASI's license. On June 10, 2010, the NRC discussed this situation with ASI management and informed ASI of the regulatory requirement to notify the NRC when a RSO permanently discontinues performance of duties in accordance with 10 CFR 35.14(b)(1) and the allowance to name ASI's AU as a temporary RSO for up to 60 days pursuant to 10 CFR 35.24(c). In a letter dated June 15, 2010, ASI provided the necessary notifications and informed the NRC that ASI had discontinued performing any nuclear medicine diagnostic tests until a new RSO was employed.

On September 17 and October 1, 2010, the NRC unsuccessfully attempted to contact ASI to determine the status of the use of licensed material and ASI's search for a new

RSO. During a telephone conversation on October 12, 2010, ASI informed the NRC that ASI resumed licensed activities, including patient studies. During this discussion, ASI was reminded of the June 10, 2010, conversation with the NRC and the option of continuing to operate under a temporary RSO for up to 60 days or converting ASI's license to a storage-only license. In addition, the NRC informed ASI that continuation of licensed activities without a permanent RSO was not permitted because the allowance to have a temporary RSO had expired on August 7, 2010.

On October 14, 2010, Region I issued ASI Confirmatory Action Letter (CAL) 1-10-001 (ADAMS Accession No.: ML102880411) requiring the immediate discontinuation of use of licensed material until a permanent RSO was authorized by the NRC, as well as the discontinuance of receipt of radioactive material from the radio-pharmacy, and lastly, to notify the NRC on the status of the RSO search and to supply a written commitment from the AU that he would continue to serve as AU for ASI. On October 21, 2010 ASI informed the NRC that the terms of the CAL were met. ASI hired a health physics consultant to serve as their RSO and their license was subsequently amended by the NRC on October 26, 2010, which authorized the consultant as ASI's new RSO. The CAL was closed on October 26, 2010 after the completion of all agreed upon actions between the NRC and ASI (ADAMS Accession No.: ML102990419).

During the on-site inspection, the inspector confirmed that ASI operated with the AU acting as temporary RSO from June 8, 2010 to August 7, 2010. The licensee restarted patient operations on August 25, 2010 and worked until October 13, 2010. As a result of this issue, ASI established a written policy stating that they would not receive radioactive material unless they have an active participating RSO. The inspector concluded that ASI operated with a temporary RSO for greater than 60 days which was not in accordance with 10 CFR 35.24(c).

The inspector noted that ASI's AU moved out of the state of West Virginia in July 2009; and returned to ASI, on a quarterly basis. Based on discussions with ASI personnel, the inspector determined that: (1) the AU had limited interactions with ASI management and returned to ASI usually on weekends to perform work activities; (2) ASI's newly hired nuclear medicine technologist (NMT) hired in August 2010 had not spoken to the AU and had not receive instructions associated with radiation protection, regulations, license conditions, or the requirement to follow the AU's instructions prior to performing nuclear medicine studies on patients; and (3) the AU's contact information posted in ASI's hot lab was incorrect.

10 CFR 35.27 states, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an AU, 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 AU for medical uses of byproduct material.

Based on the observations by the inspector, the NMT had a discussion with the AU on April 29, 2011. An official training session was held between the AU, the owner of the practice, and the NMT on May 30, 2011. ASI updated all contact information for the AU,

RSO, owner, and technologist and posted it in their Emergency Contact list in their hot lab. The inspector concluded that the AU did not provide adequate supervision of individuals permitted to receive, possess, and use nuclear material under the supervision of ASI's AU, as required by 10 CFR 35.27.

During a review of records, the inspector noted that ASI had administered dosages that differed from the prescribed dosage by more than 20% without being directed by the AU as required by 10 CFR 35.63(d). Specifically, the AU had prescribed dosages for Technetium-99m (Tc-99m) of 40 mCi and 13 mCi for cardiac stress and rest tests, respectively. During the Tc-99m shortage in 2010, the pharmacy routinely supplied ASI with 30 mCi for stress tests and 10 mCi for rest tests. These dosages were administered to the patients by the NMT without approval from the AU. Based on the observation by the inspector, ASI developed a revised administered dosage procedure and instructed ASI personnel on the procedure during a training session by the AU on May 30, 2011. The RSO also reviewed the revised dosage procedures with ASI personnel on May 31, 2011. The inspector concluded that ASI administered dosages that differed from the prescribed dose by more than 20% without being directed by the AU, as required by 10 CFR 20.1101(c).

The inspector also noted that ASI's first audit of their radiation protection program was completed on January 3, 2011. The audit consisted of a review of records between August and December 2010. 10 CFR 20.1101(c) requires that the licensee periodically (at least annually) review the radiation protection program content and implementation. The inspector determined that an audit should have been performed which reviewed ASI's radiation protection program for calendar years 2009 and 2010. Based on the observations by the inspector, ASI completed a full audit on June 13, 2011, which reviewed their program for calendar year 2010. The inspector concluded that ASI did not perform an annual review (audit) of their radiation protection program, as required by 10 CFR 20.1101(c).

Facilities and Equipment

ASI relocated to a new base location on April 11, 2011. The inspector noted that ASI did not perform accuracy, geometry and linearity testing after moving and prior to using the dose calibrator on April 11, 2011, at their new facility. 10 CFR 35.60(b) states, in part, that a licensee shall calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions.

Based on the observation by the inspector during the on-site inspection, ASI suspended use of the dose calibrator and used a decay calculation method to assay their patient doses prior to administration until ASI was able to complete dose calibrator linearity, accuracy, and geometry testing on April 28, 2011. ASI also trained the NMT on the dose calibrator testing procedures on May 31, 2011. The inspector concluded that ASI did not perform accuracy, geometry, and linearity testing after moving and prior to using their dose calibrator at their new facility, as required by 10 CFR 35.60(b).

Material Receipt, Use, Transfer, and Control

Based on discussions with ASI personnel, review of records, and observations, the inspector determined that package surveys were properly performed and appropriately documented.

Training of Workers

Based on a review of records and discussions with ASI personnel, the inspector noted that ASI's NMT received HAZMAT and radiation safety training on January 3, 2011. The NMT had responsibilities associated with ASI's nuclear medicine and mobile nuclear medicine operations. The NMT started employment at ASI on August 16, 2011. The inspector concluded that ASI did not provide HAZMAT training within 90 days of when an ASI employee started employment as a mobile NMT, as required by 49 CFR 172.704(c)(1)(ii).

The inspector also noted that upon the new RSO assuming responsibilities, he provided ASI personnel the required radiation safety and HAZMAT training; and that ASI did not have any documented records for providing radiation safety and HAZMAT training to ASI personnel prior to the January 2011 training.

Radiation Surveys

Based on discussions with ASI personnel, review of records, and observations, the inspector determined that radiation surveys of areas where nuclear material was used were properly performed and appropriately documented.

Radiation Protection

During a review of ASI radiation protection procedures, the inspector determined that ASI did not have procedures for survey meter calibrations, area surveys, and mobile emergency response procedures. ASI had committed to develop and maintain these procedures during their original license application. These commitments were "tied-down" per Condition 15 of ASI's license. Based on the observations by the inspector, ASI developed mobile emergency and area survey procedures. ASI submitted a copy of these procedures to the NRC on May 30, 2011. As part of their corrective actions, ASI submitted an amendment request to change their license commitments contained in their original license application. The amendment requested that ASI would not perform survey meter calibrations. Instead, radiation monitoring instruments would be calibrated by a person qualified to perform survey meter calibrations. Specifically, survey meters will be sent off-site for calibration. ASI also trained their personnel on the revised procedures on May 31, 2011. The inspector concluded that ASI did not have written procedures for survey meter calibrations, area surveys, and mobile emergency procedures, as required by Condition 15 of ASI's license.

Radioactive Waste Management

Based on discussions with ASI personnel, review of records, and observations, the inspector determined that radioactive waste with a half-life of less than 120 days was being properly held for decay-in-storage and was appropriately surveyed prior to disposal.

Transportation

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.

The inspector noted that ASI did not list a Cobalt-57 flood source, that was being transported in their mobile van, on its shipping papers as required by 49 CFR 172.203(d). The inspector determined that the flood source would not be considered an excepted package for limited quantites of Class 7 (Radioactive) packages, because the radiation level at any point on the external surface of the package would exceed 0.005 mSv/hour (0.5 mrem/ hour) as stated in 49 CFR 173.421(a)(2). Specifically, the flood source read 1.5 mrem/hour at the surface based on direct measurement by the inspector. Based on the inspector's observation, ASI discontinued transport of the Cobalt-57 flood source. The inspector concluded that ASI did not list a Cobalt-57 flood source on its shipping papers, as required by 49 CFR 172.203(d).

The inspector also noted that ASI did not properly store shipping papers within their mobile van, as required by 49 CFR 177.817(e)(2)(i). The regulations require that when the driver is at the vehicle's controls, the shipping paper shall be: (a) within their immediate reach while the driver 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. The inspector determined that the shipping papers were being stored on the outside of a Type A container which was kept in the back of the mobile van. As of May 10, 2011, ASI committed that personnel would keep shipping papers within arm's reach of the driver. The inspector noted that the RSO retrained ASI personnel of the location of shipping papers during transit on May 31, 2011. The inspector concluded that shipping papers were not being properly stored within ASI's mobile van, as required by 49 CFR 177.817(e)(2)(i).

c. Conclusions

The inspector identified nine apparent violations of NRC requirements. Specifically,

- ASI permitted an AU to function as temporary RSO for a period greater than 60-days, which was not in accordance with 10 CFR 35.24(c). Specifically, after ASI's RSO left the company on June 8, 2010, the AU functioned as the temporary RSO until October 13, 2010. The NRC issued a CAL on

October 14, 2010, which suspended operations until a license amendment was issued with a new RSO established.

- ASI did not ensure that adequate supervision was provided to individuals under the supervision of the AU, as required by 10 CFR 35.27. Specifically, the AU had moved out of state in July 2009 and as a result had limited oversight of the program. From August 16, 2010 to April 19, 2011, new ASI personnel under the supervision of the AU had not spoken to the AU 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 AU for medical uses of byproduct material.

- ASI did not periodically (at least annually) review the radiation protection program content and implementation, as required by 10 CFR 20.1101(c). Specifically, ASI did not perform an audit of their radiation safety program for calendar year 2009 and the 2010 audit was limited and only included a review of activities conducted during the fourth quarter of 2010.

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- ASI did not calibrate a dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions, as required by 10 CFR 35.60(b). Specifically, ASI did not perform accuracy, geometry and linearity testing after moving and prior to using the dose calibrator on April 11, 2011, at their new facility.

- ASI did not have the procedures they committed to develop and maintain per Condition 15 of their NRC license (47-31344-02). Specifically, 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. As of April 19, 2011, ASI had not developed these procedures.

- ASI did not properly store shipping papers within their mobile van when they were transporting radioactive material as required by 49 CFR 177.817(e)(2)(i). Specifically, shipping papers were not within the driver's immediate reach and were not readily visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the driver's side of the vehicle. The shipping papers were stored on the outside of the Type A container which was kept in the back of ASI's mobile van.

- ASI did not provide training to personnel associated with their mobile nuclear medicine operations, as required by 49 CFR 172.704(c)(1)(ii). Specifically, ASI did not provide HAZMAT training within 90 days of when an ASI employee started employment as a mobile nuclear medicine technologist. The nuclear medicine technologist started their employment with ASI on August 16, 2010, and did not receive HAZMAT training until January 3, 2011.

- ASI did not list all nuclear material being transported in their mobile van on their shipping papers, as required by 49 CFR 172.203(d). Specifically, a Cobalt-57 flood source was not listed on ASI's shipping papers.

The inspector reviewed the corrective actions documented by ASI in the additional information, they provided in correspondence on May 2, 10, 30, and 31, 2011 and June 13 and 28, 2011. The inspector found ASI's actions to be prompt and comprehensive.

EXIT MEETING

At the conclusion of the on-site inspection on April 19, 2011, the inspector discussed the observations with ASI management. On May 3, 2011, a conference call was conducted with Saad Mossallati, M.D., owner and Medical Director of ASI, and Mark Perna, RSO, to discuss the preliminary inspection findings. ASI acknowledged the inspector's findings and immediately initiated corrective actions. An exit meeting was held by telephone on August 16, 2011, with Dr. Saad Mossallati and Mark Perna, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

#Amber Wright, Nuclear Medicine Technologist
#*+Saad Mossallati, M.D., Owner/Medical Director
*+Mark Perna, Radiation Safety Officer

#present at entrance meeting
*present at preliminary exit meeting
+present at final exit meeting