

April 16, 2010

Pramod Raval, M.D., P.C.
Pramod Raval, M.D.
24461 Coolidge Highway
Oak Park, MI 48237

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-36030/10-01(DNMS) AND
NOTICE OF VIOLATION – PRAMOD RAVAL, M.D., P.C.

Dear Dr. Raval:

On March 16, 2010, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at your facility in Oak Park, Michigan. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a concern regarding a letter dated February 26, 2010, to remove the Radiation Safety Officer from the license. The enclosed report presents the results of the inspection.

The inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of the inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

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 violations are being cited in the Notice because they were identified by the NRC.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in Inspection Report No. 030-36030/10-01(DNMS). Therefore, you are not required to respond to this letter unless the description herein 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 will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management 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, proprietary, or safeguards information so that it can be made available to the public without redaction.

Sincerely,

/RA/

Tamara Bloomer, Chief
Materials Inspection Branch

Docket No. 030-36030
License No. 21-32401-01

Enclosures:

1. Notice of Violation
2. Inspection Report 030-36030/10-01(DNMS)

Cc: Ray Carlson, RSO
State of Michigan

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in Inspection Report No. 030-36030/10-01(DNMS). Therefore, you are not required to respond to this letter unless the description herein 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.

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Cc: Ray Carlson, RSO
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NOTICE OF VIOLATION

Pramod Raval, M.D., P.C.
Oak Park, MI

Docket No. 030-36030
License No. 21-32401-01

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 16, 2010, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.24(b) requires that a licensee's management appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

Contrary to the above, between February 26, 2010 and March 16, 2010, the licensee's management failed to appoint a Radiation Safety Officer, who agreed, in writing, to be responsible for implementing the radiation protection program.

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

- B. 10 CFR 35.14(b)(1) requires the licensee, in part, to notify the Commission no later than 30 days after an authorized user permanently discontinues performance of duties under the license.

Contrary to the above, the licensee's only authorized user, had permanently discontinued his performance of duties during January 2010, and the licensee did not notify the NRC until March 16, 2010, a time period more than 30 days after the authorized user had discontinued his performance of duties.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in NRC Inspection Report 030-36030/10-01(DNMS). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein 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" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Notice of Violation

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If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from NRC's Agencywide Documents Access and Management 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, 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.

Dated this 16th day of April 2010.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-36030

License No.: 21-32401-01

Report No.: 030-36030/10-01(DNMS)

Licensee: Pramod Raval, M.D., P.C.

Location: 24461 Coolidge Highway
Oak Park, MI 48237

Date of Inspection: March 16, 2010 (On-site)

Inspector: Robert P. Hays, Health Physicist

Reviewed By: Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

**Pramod Raval, M.D., P.C.
Oak Park, Michigan
Inspection Report No. 030-36030/10-01(DNMS)**

This was a reactive inspection to review the circumstances, root and contributing causes, and corrective actions associated with a license amendment request from the Radiation Safety Officer, (RSO) listed on the license to remove him as the RSO without the license amendment including a request to add another individual as RSO to the license. The RSO was contacted by a license reviewer to determine if another RSO would be added to the license. The RSO informed the license reviewer that he was no longer affiliated with the licensee and was uncertain as to who the licensee would appoint as the next RSO. No letter or amendment request had been received from the licensee notifying the Commission of a change in RSO. The RSO was also asked about an additional location, Hamtramck, Michigan, listed on the license. The RSO informed the license reviewer that the location had been closed, but was not sure if any licensed material remained at the facility. Because of the uncertainty of the licensee's current RSO and if any licensed material remained at the Hamtramck, Michigan facility, a reactive inspection was conducted March 16, 2010, to determine the status of licensed activities authorized by License No. 21-32401-01.

The inspection identified two violations of the U.S. Nuclear Regulatory Commission (NRC) requirements involving: (1) a failure by the licensee's management to appoint a RSO, who agrees, in writing, to be responsible for implementing the radiation protection program; and (2) a failure to notify the Commission no later than 30 days after an authorized user (AU) permanently discontinues performance of duties under the license. During the inspection, the licensee took immediate corrective actions by obtaining the services of a consulting RSO to assume the duties of RSO for the licensee and replacing the AU listed on the license with another AU physician who agreed to be the replacement AU.

Report Details

1 Program Scope and Inspection History

NRC License Number 21-32401-01 authorizes Pramod Raval, M.D., P.C. (licensee) to use any by-product material for any uptake, dilution and excretion study permitted by Title 10 CFR 35.100 and to use any by-product material for imaging and localization study permitted by 10 CFR 35.200. The licensee used by-product material for cardiac patient studies. Patient cardiac studies were performed by the licensee on Tuesdays and Saturdays each week at the Oak Park, Michigan Office.

The licensee was issued a new license on August 7, 2002. The licensee's inspection history includes an initial inspection conducted on August 11, 2003, with no violations of NRC requirements identified. A subsequent inspection conducted on June 3, 2008, with no violations identified during that inspection.

2 Determination of Radiation Safety Officer and Authorized User

2.1 Inspection Scope

The inspector performed an unannounced inspection at the licensee's Oak Park, Michigan office to determine if the licensee had appointed another RSO to replace the RSO who had submitted the license amendment request to remove his name from the license. The inspection also determined if the licensee's only AU listed on the license was still performing licensed activities as authorized by the license. The inspector interviewed the physician, Pramod Raval, M.D., to whom the license was issued.

2.2 Observations and Findings

On March 16, 2010, Dr. Raval was interviewed to determine if the licensee had appointed a RSO to replace the RSO, William J. Messina, CNMT, listed on the license who had submitted a license amendment request letter dated February 26, 2010, to remove his name from the license. Dr. Raval informed the inspector that he had planned to appoint a consulting physicist as the replacement RSO, but was unable to pay the required fee to the consulting physicist until Medicare reimbursements had been received. Title 10 CFR 35.24(b) requires that a licensee's management appoint a RSO, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, is required to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The licensee's failure to appoint a RSO to replace the RSO listed on the license between February 26, 2010 and March 16, 2010 is a violation of 10 CFR 35.24(b).

The inspector also questioned Dr. Raval about the AU, Ashok Jain, M.D., listed on the license as the only AU. Dr. Raval stated that Dr. Jain had left the practice some time during January 2010 to go to work for a hospital. The inspector informed Dr. Raval that Dr. Jain was the only AU listed on the license and another AU would have to be added to the license. Dr. Raval was unaware that another AU had to be added to the license. Since the license had been issued to Dr. Raval, Dr. Raval believed that he was also an

AU for the license. Title 10 CFR 35.14(b)(1) requires the licensee, in part, to notify the Commission no later than 30 days after an AU permanently discontinues performance of duties under the license. The licensee's failure to notify the NRC that the AU had permanently discontinued the performance of his duties during January 2010, and the licensee did not notify the NRC until March 16, 2010, is a violation of Title 10 CFR 35.14(b)(1).

2.3 Conclusions

The inspector identified a violation of 10 CFR 35.24(b) for failure to appoint a RSO to replace the RSO listed on the license between February 26, 2010 and March 16, 2010. A violation of 10 CFR 35.14(b)(1) was also identified for a failure to notify the NRC that the AU had permanently discontinued the performance of his duties during January 2010, and the licensee did not notify the NRC until March 16, 2010.

3 **Licensee Corrective Actions**

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude a similar violation. The review included an interview with the licensee, Pramod Raval, M.D., to whom the license was issued.

3.2 Observations and Findings

After the inspector had informed Dr. Raval that he was in violation of NRC requirements for not having a RSO and an AU, Dr. Raval contacted Won Chae, M.D., a physician who is listed as an AU on other NRC licenses. Dr. Chae agreed to be added to Dr. Raval's license as an AU. Dr. Chae also recommended to Dr. Raval to contact Ray Carlson about being added to the license as the RSO. Dr. Raval contacted Ray Carlson during the inspection and Ray agreed to be appointed and serving as the RSO on Dr. Raval's license. A license amendment request to change the RSO to Ray Carlson and add Dr. Chae as the AU on the license was subsequently faxed to Region III. An amendment to Dr. Raval's license was issued on March 17, 2010, reflecting the change in RSO and AU.

3.3 Conclusions

The inspector determined that the licensee had taken immediate corrective actions to address the violations.

4 **Other Areas Inspected**

4.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation safety program by reviewing selected licensee records, including receipt and use of licensed material, package surveys, survey instruments, constancy tests of the dose calibrator, and other associated equipment, security of licensed material, and discussions with the nuclear medicine technologist (NMT).

4.2 Observations and Findings

The licensee performed all required constancy tests of equipment on each day of use. Packages containing unit doses were tested for contamination as required when received and documented. Records also indicated that activity of each dose was assayed prior to administration. The NMT informed the inspector that licensed activities at the Hamtramck, Michigan office had been terminated with closeout surveys being done and check sources used for testing equipment had been transferred to the Oak Park, Michigan office. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

4.3 Conclusions

No violations of NRC requirements were identified.

5 **Exit Meeting Summary**

The inspector discussed the violations as described in this report, with Dr. Raval during the exit meeting conducted at the licensee's facility on March 16, 2010. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

List of Persons Contacted

* Pramod Raval, M.D., Licensee
Andre Scales, Nuclear Medicine Technologist
Won Chae, M.D., proposed Authorized User
Ray Carlson, proposed Radiation Safety Officer

* Attended the March 16, 2010, exit meeting