

INSPECTION RECORD

Region III Inspection Report No. 030-33202/11-01(DNMS)

License No. 21-20358-02
Docket No. 030-33202

Licensee:
Downriver X-Ray & Nuclear Diagnostics
18600 Van Horn Road
Woodhaven, Michigan 48183

Licensee Contact: Josephine J. Finazzo, D.O, Radiation Safety Officer
Telephone No. 734-675-0304

Priority: 5 Program Code: 2201

Date of Last Inspection: 04/27/2006 Date of This Inspection: 03/23/2011 with continued
in-office review through
04/04/11 to review the
licensee's use of extremity
dosimetry

Type of Inspection: Initial Announced Unannounced
 Routine Special

Next Inspection Date: 3/2016 Normal Reduced

Summary of Findings and Actions:

- No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- Non-cited violations (NCVs)
- Violation(s), Form 591 issued
- Violation(s), regional letter issued
- Followup on previous violations

Inspector: Andrew M. Bramnik
Andrew M. Bramnik, Health Physicist

Date: 4/8/11

Approved: Tamara E. Bloomer
Tamara E. Bloomer, Chief,
Materials Inspection Branch

Date: 4/8/11

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>Amendment No.</u>	<u>Date</u>	<u>Subject</u>
2	3/29/2010	New RSO (Dr. J. Finazzo) listed
1	3/28/2004	License renewed in entirety

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations were identified during prior inspections on April 27, 2006, and October 5, 2000.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Management Structure:

Dr. J. Finazzo, Radiation Safety Officer (RSO)
Bill Schave, Office Administrator and X-Ray Technologist
Mayur Vaya, Part Time Nuclear Medicine Technologist

The licensee operated a private clinic that performed approximately 20 diagnostic nuclear medicine procedures per month. One part time nuclear medicine technologist performed all patient procedures between one and four days each month, when patients were scheduled. The licensee did not routinely perform nuclear medicine studies on a daily basis. The licensee obtained licensed material as unit doses from an area nuclear pharmacy, and did not use xenon-133, bulk doses, or molybdenum/technetium generators. The licensee performed primarily cardiac scans, as well as occasional thyroid scans, and was not authorized to perform or administer therapeutic doses.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: Sections 03.01 through 03.07

Interviews of available staff revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures were also demonstrated.

Personal whole body dosimetry was observed being worn by the staff during the inspection, and records did not indicate doses in excess of limits in Title 10 of the Code of Federal Regulations (10 CFR) Part 20. Dosimetry records indicated that the highest annual whole body reading for the past four years was 298 millirem (mrem). An evaluation of licensee's nuclear medicine technologist's exposure history determined that he was not likely to receive, in one year, an extremity dose greater than 10 percent of the allowable limits in 10 CFR 20.1201. Therefore, he was not required to wear extremity dosimetry. However, the technologist wore his extremity dosimeter from Henry Ford Wyandotte Hospital whenever handling radioactive materials at Downriver X-Ray and Nuclear Diagnostics. The technologist's dosimetry records indicated that his highest extremity reading for the past four years was 480 mrem for activities performed at both locations.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Independent measurements taken did not indicate readings in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. The licensee possessed a radiation survey meter that was calibrated, operational, and performed well in side-by-side comparison with an NRC instrument.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Title 10 CFR 35.14(b)(1) states, in part, that a licensee shall notify the Commission no later than 30 days after an Authorized User permanently discontinues performance of duties under the license.

Contrary to the above, between May 2010 and April 4, 2011, the licensee failed to notify the Commission within 30 days of two Authorized Users listed on NRC License No. 21-20358-02 who permanently discontinued performance of duties under the license. Specifically, on or about March 29, 2010, two Authorized Users listed on the license had permanently discontinued performance of duties under the license and the licensee had as of April 4, 2011, not yet notified the Commission. During this period the licensee did not have any Authorized Users listed on its license who were affiliated with the licensee. During this same period the Radiation Safety Officer, who was a technically qualified individual and was approved as an Authorized User on another NRC license, performed the functions of an Authorized User for the licensee, consistent with 10 CFR 35.13(b)(4)(i).

The root cause of the violation was the licensee's lack of awareness of the requirements to notify the NRC when an Authorized User permanently discontinues performance of duties under the license. Specifically, the licensee thought that a March 29, 2010 license amendment request to add Dr. Finazzo as the RSO was sufficient to add her as an Authorized User, and that they did not need to modify their license to remove two Authorized Users who had discontinued performance of duties under the license.

As corrective actions, the licensee will submit a license amendment request to the NRC removing two individuals from its license and adding Dr. Finazzo as an Authorized User. As stated above, Dr. Finazzo is listed as an Authorized User and RSO for materials under 10 CFR 35.100 and 35.200 on other NRC licenses. This request will be

sent to the NRC by April 22, 2011. The licensee is now aware of the requirement in 10 CFR 35.14, and committed to maintain the license. The licensee does not expect any changes in Authorized Users in the near future, and informed the inspector that they may terminate their NRC license at the end of 2011 because they do not plan to pursue accreditation through the American College of Radiology (ACR).

5. PERSONNEL CONTACTED:

- * Bill Schave, Office Administrator and X-Ray Technologist
- * Mayur Vaya, Part Time Nuclear Medicine Technologist
- # Josephine Finazzo, RSO

Use the following identification symbols:

- * Individual present at March 23, 2011 preliminary on-site exit meeting
- # Individual present at April 4, 2011, telephone exit meeting

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