

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
73	12/16/2014	Revised locations of use, new RSO
72	07/20/2014	Revised locations of use
71	05/02/2014	License renewal
70	02/13/2014	Revised locations of use
69	12/03/2013	Revised locations of use
68	09/05/2013	Revised locations of use
67	06/24/2013	Revised locations of use
66	06/03/2013	Renamed facilities
65	04/02/2013	Renamed facilities

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last inspected Nuclear Diagnostics, Inc. on September 12, 2012, and prior to that on June 9, 2009. No violations of NRC requirements were identified as a result of either inspection.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Nuclear Diagnosis, Inc. is authorized by NRC Materials License No. 24-17561-01 to conduct diagnostic and therapeutic administrations of radiopharmaceuticals at eight facilities throughout southwest Missouri, and at temporary job sites in NRC jurisdiction. The licensee performs diagnostic administrations each weekday at its facilities in Branson (both locations), Carthage, Monett, and Sullivan; Monday and Thursday only at the facility in Aurora; and Tuesday, Wednesday and Friday only at the facility in Cassville. The licensee's main office in Springfield is generally unoccupied and is used infrequently for package receipt and leak test analysis.

Although authorized for therapeutic administrations, the licensee has not performed any to date, and has no plans to do so in the future. The licensee has not conducted any activities under its license at temporary job sites since the last inspection.

The licensee retains the services of a medical physics consultant, primarily for commissioning and decommissioning of facilities. The licensee's NMT manager performed leak tests, inventories, and quarterly audits, while on-site technologists performed routine instrument quality control.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All

The inspector toured the licensee's facilities in Branson (251 Skaggs Road), Carthage, Monett, and Cassville, Missouri, to evaluate the licensee's measures for material security, hazard communication and exposure control.

The inspector observed the preparation and administration of one cardiac stress test and one bone scan while on-site. The licensee's staff also demonstrated the implementation of package receipt, area survey, spill response and waste handling procedures at each facility.

Through interviews with the NMT manager and several other technologists, the inspector found that the licensee's staff was knowledgeable and conscientious of radiation protection principles and licensee procedures for administration of radiopharmaceuticals.

The inspector reviewed a selection of licensee records for package receipt, dose preparation, area and personnel surveys, waste handling, sealed source inventory and leak testing, dose calibrator quality control, hazmat training and dosimetry.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Canberra UltraRadic survey instrument (calibrated on July 21, 2014) the inspector conducted independent and confirmatory surveys at each of the locations inspected. The independent surveys found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits, while the confirmatory surveys demonstrated that licensee staff used appropriate survey instruments and techniques.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

On December 16, 2014, the inspector identified a violation of 10 CFR 20.1906(d)(1) for the licensee's failure to notify the final delivery carrier and the NRC Operations Center when removable radioactive surface contamination on labeled packages containing radioactive material exceeded the limits set by the U.S. Department of Transportation (DOT).

Specifically, on two separate occasions since January 1, 2013, the licensee's staff at Cox Medical Center in Branson, Missouri recorded measurements of removable contamination on packages that exceeded the limit of 2200 dpm per 100 cm², as specified in 49 CFR 173.443 for gamma emitting radionuclides, assuming a wipe efficiency of 0.10. On April 23, 2014, the licensee measured 7276 dpm per cm² on a package containing unsealed quantities of technetium-99m (Tc-99m), labeled as Radioactive White I. On June 25, 2014, the licensee measured 2247 dpm per cm² on another package containing unsealed quantities of Tc-99m, also labeled as Radioactive White I. On neither occasion did the licensee notify the final delivery carrier (Zevacor in Springfield, Missouri) or the NRC Operations Center that the measured contamination exceeded the DOT limit.

The licensee's staff in Branson indicated that they relied on the well counter to determine whether a package exceeded the limits for contamination. The inspector found that the well counter would alert the user when a measurement exceeded a certain limit; however, that limit was set at 20,000 dpm per 100 cm². Had the licensee factored for wipe efficiency (i.e. multiplied the actual measurements by 10), this limit would have been appropriate. However, the staff was not previously aware of the concept of wipe efficiency, and thus to compensate for the absence of a wipe efficiency factor in the measurement, the limit should have been reduced by the same factor. Because it was not, any measurement between 2200 and 19999 dpm per 100 cm² would have technically exceeded the DOT limit, but would not have been flagged by the well counter.

The inspector found that the licensee's nuclear medicine computer tracking system, into which daily measurements such as package surveys were entered, would have alerted the user when a contamination measurement exceeded only 2000 dpm per 100 cm². However, the pop-up notification appeared to have been interpreted more as a confirmation than an alert, and did not specifically prompt the user to report the package as contaminated.

The inspector reviewed the procedure in place at Cox Medical Center in Branson for safely opening packages containing radioactive material. In section I, the procedure stated that "*the NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm/100 cm²).*" The procedure did not indicate whether this limit should be compared to the actual measurement or one which factors for wipe efficiency.

The inspector also reviewed area survey results for April 23 and June 25, 2014. Neither survey indicated the presence of residual contamination in the areas surveyed, including the hot lab, where packages were received and stored.

The individuals whom the inspector interviewed, including the NMT manager and the RSO, were generally aware that the limit for removable contamination should be about 2000 dpm per 100 cm². The inspector determined, therefore, that the root cause of the violation was an oversight, in that the technologists accepted the well counter's pass/fail determination at face value without realizing that the measurement was actually in excess of the DOT limit for contamination.

As corrective actions to restore compliance, the NMT manager committed to notifying the final delivery carrier of the occurrences. As corrective action to address recurrence, the NMT manager also committed to addressing the discrepancy with the instrument's action level, to addressing a similar discrepancy in the facility's procedures for safely opening packages containing radioactive material, and to discussing the requirements for measurement of removable contamination with staff.

5. PERSONNEL CONTACTED:

- * Larry Albaugh, NMT Manager
Greg Bun, Nuclear Medicine Technologist
- # Charles Hillis, Radiation Safety Officer
Eduardo Juncos, Nuclear Medicine Technologist
Kevin Peterson, Nuclear Medicine Technologist
Matt Pritchard, Nuclear Medicine Technologist
Troy Thompson, Nuclear Medicine Technologist

- * Attended preliminary exit meeting by telephone on December 19, 2014
- # Attended final exit meeting by telephone on December 22, 2014

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