



## **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>
68	03/19/14	Reduced possession limits
67	08/09/13	Removed authorization for P-32 and P-33, changed authorization for H-3 to storage only
66	06/05/12	Removed authorization for Am-241 foils
65	06/06/11	Revised licensee's name
64	03/22/11	Replaced RSO

### 2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last conducted a routine inspection MRI Global on March 16, 2011, when it was known as the Midwest Research Institute. As a result of that inspection, the NRC identified three violations relating to (1) the failure to make surveys to assure compliance with regulations regarding internal exposure and dose limits to members of the public; (2) the failure to adequately label a contaminated filtration system; and (3) the failure to conduct a physical inventory of a tritium foil source.

Prior to that, the NRC conducted a routine inspection of this licensee on January 28, 2005. No violations of NRC requirements were identified as a result of this 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:

MRI Global was a contract research organization authorized to use byproduct material for research and development at its facility in Kansas City, Missouri. At the time of the inspection, the licensee had one active authorized user who occasionally performed radiochemical synthesis using millicurie quantities of C-14. The licensee also stored millicurie quantities of C-14 on behalf of other organizations, and possessed a number of electron capture detectors (ECDs) for use in gas chromatographs under its specific license. In total, the licensee possessed 20 ECDs, of which only four were in service at the time of the inspection. These four, as well as 15 of the devices in storage, contained Ni-63 foils. The last ECD in storage contained H-3 in the form of scandium tritide. The licensee's RSO maintained oversight of the radiation safety program with the assistance of a safety technician.

### 2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: All

The inspectors toured several areas of the Kansas City facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors were unable to observe any radiochemical synthesis, but were instead able to observe the use of gas chromatographs ECDs containing Ni-63. The inspectors interviewed a number of licensee staff, and discussed the implementation of various licensee procedures, including safe use of unsealed radioactive material, area surveys and contamination control, material accountability, bioassays, waste handling, and shipping and receiving of radioactive material. Through these discussions, the inspectors found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspectors also reviewed a selection of the licensee's records, including bioassay procedures, area survey results, sealed source inventories and leak tests, receipts of packages containing radioactive material, dosimetry reports, hazardous materials transportation training records, and annual audits of the radiation safety program.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector calibrated on January 5, 2015, the inspectors conducted independent surveys in restricted and unrestricted areas of the licensee's Kansas City facility. The inspectors found no evidence of residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Leak Testing of Operational Sources

During a review of the licensee's leak test records, the inspectors identified a violation of Condition 13.A of Materials License 24-02564-02 for the failure to test operational sealed sources for leakage and/or contamination at intervals not to exceed 6 months. Specifically, the inspectors found that the licensee had not tested four sources of Ni-63 in the operational ECDs between June 4, 2013 and August 20, 2015.

The licensee confirmed with the company who provided leak test analysis services that the sources were routinely tested every six months only until June 2013. The licensee provided documentation showing that it had collected leak tests in August 2015, and was still waiting for the results from the service provider.

The inspectors determined that the root cause of this violation was a lack of adequate oversight for the sources contained in ECDs. As corrective action, the licensee committed to provide the results of the August 2015 leak tests to the NRC, and to set electronic calendar reminders to ensure that future leak tests of operational sources were performed at intervals not to exceed 6 months.

B. Leak Testing of Sources in Storage

During a review of the licensee's leak test records, the inspectors identified a violation of Condition 13.C of Materials License 24-02564-02 for the failure to test

sealed sources in storage for leakage and/or contamination at intervals not to exceed 10 years. Specifically, the inspectors found that the licensee had not tested four Ni-63 sources since removing them from service and placing them in storage between October 1991 and November 2001. Of the remaining 12 sources in storage, the licensee had placed five of them there within the last 10 years, conducting leak tests of each on the date of storage. For the other seven sources, the licensee did not know when each had been placed in storage, or when they had last been tested.

The inspectors determined that the root cause of this violation was a lack of adequate oversight for the sources contained in ECDs. As corrective action, the licensee committed to collect and submit for analysis leak tests of all ECDs in storage, and to set electronic calendar reminders to ensure that future leak tests of sources in storage were performed at intervals not to exceed 10 years.

#### C. Physical Inventories

During a review of the licensee's inventory records, the inspectors identified a violation of Condition 19 of NRC Materials License 24-02564-02 for the failure to conduct a physical inventory of all sealed and/or foil sources at intervals not to exceed 6 months, or at other intervals approved by the NRC, to account for all sources and/or devices received and possessed under the license. Specifically:

- The licensee did not account for the four sources of Ni-63 in operational ECDs between June 4, 2013 and August 20, 2015, the dates of the two most recent leak tests of these sources.
- The licensee only accounted for the 16 sources in storage once since January 7, 2011 (on January 21, 2014).

The inspectors determined that the root cause of this violation was a lack of adequate oversight for the sources contained in ECDs, with ineffective corrective actions from a previous but similar violation (see below) as a contributing factor. As further corrective action, the licensee committed to conduct a physical inventory of all sources possessed under the license, and to set electronic calendar reminders to ensure that future physical inventories were performed at intervals not to exceed 6 months. The licensee also stated that it would investigate the potential for disposing of the in-storage ECDs in the coming fiscal year.

#### D. Closure of previous violations

The inspectors reviewed the implementation and effectiveness of the licensee's corrective actions taken in response to three violations previously identified in IR 03005083/2011001(DNMS).

For the violation relating to the failure to make surveys to assure compliance with regulations regarding internal exposure and dose limits to members of the public, as well as the violation relating to the failure to adequately label a contaminated filtration system, the inspectors found that the licensee took actions as described in their response dated April 15, 2011. The inspectors found these corrective actions to be adequate and found that these violations were non-recurring; therefore the NRC considers these violations to be closed.

However, for the violation relating to the failure to the failure to conduct a physical inventory of a tritium foil source, the inspectors found that while the licensee did initially take action as described in their response, it did not continue to take this action at the required intervals. The inspectors also identified a similar violation for failure to conduct inventories of other sources; therefore the NRC considers this third violation to remain open for review during a future inspection.

5. PERSONNEL CONTACTED:

Christian Bailey – Manager, Quality & Regulatory Systems

Peter Deardorff – Authorized User

# Eric Jeppesen – Manager, Environmental, Health & Safety Office

Clint Wiley – Safety Technician

# Attended exit meeting on September 18, 2015.

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