

INSPECTION RECORD

Region III Inspection Report No. 030-34052/2011-002
License No. 13-24532-02 Docket No. 030-34052

Licensee (Name and Address):
Roche Diagnostics Operations, Inc.
9115 Hague Road
Indianapolis, Indiana 4620

Licensee Contact: Thomas Schumacher - RSO Telephone No. 317-902-9868

Priority: 2410 Program Code: 5

Date of Last Inspection: July 2011

Date of This Inspection: 8/1/2011 through 9/12/2011

Type of Inspection: ☐ Initial ☐ Announced ☐ Unannounced
☐ Routine ☒ Special (Decommissioning)

Next Inspection Date: No Change ☐ Normal ☐ Reduced

Justification for reducing the routine inspection interval:

Decommissioning Related – does not change routine inspection frequency or schedule.

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 Michael LaFranzo
Michael LaFranzo – Senior Health Physicist

Date 9/22/11

Approved Christine A. Lipa
Christine A. Lipa, Chief, MCID

Date 9-26-11

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

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No. Date Subject

No amendment changes regarding decommissioning in last 5 years.

2. INSPECTION AND ENFORCEMENT HISTORY:

Routine inspection on 7/18/2011: No violations identified.

Routine inspection on 10/31/2005: No violations identified.

Routine inspection on 12/5/2003: 10 CFR 30.36(j)(2). Failure to submit written results of "close-out" surveys would be considered a violation of 10 CFR 30.36(j)(2). However, since the licensee's surveys identified no radiation levels above background, the NRC finds no health and safety concern associated with the release and considers it to be a violation of minor safety significance in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-7600.

3. INCIDENT/EVENT HISTORY:

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Jack Phillips – President

Tom Adkins – Senior Vice President

Kevin Gara – Director of Safety, Health and Environmental Protection

Thomas Schumacher – Radiation Safety Officer

The licensee was authorized to use and store licensed material for in-vitro laboratory experiments. The licensee ceased all principal activities in February 2009. The licensee normally used millicurie quantities of licensed material at irregular intervals in the past.

2. SCOPE OF INSPECTION:

The telephonic inspection focused on a follow up of information identified during a routine inspection conducted on July 18, 2011. Specifically, the inspection report stated that the licensee had stopped using radioactive material and had decommissioned the site. The inspection was to determine whether the licensee was complying with decommissioning NRC requirements.

Inspection Procedure(s) Used: 87104

Focus Areas Evaluated: 03.01

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

There was not site inspection and, therefore, no independent or confirmatory measurements made during this inspection. Future inspections may warrant these measurements to confirm residual licensed material at facility.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

On July 18, 2011, a routine inspection was performed and identified that the licensee had stopped using radioactive material and had decommissioned its site. On August 1, 8, and 9, 2011, Region III contacted the licensee, via telephone, to determine if the licensee had ceased principal activities under the license. During the telephonic conversations, Region III identified that the licensee had ceased principal activities in February 2009.

A telephonic exit meeting was held with members of your staff and Michael LaFranzo on September 12, 2011. Based upon that information, the NRC identified that the licensee was in violation of 10 CFR 30.36(d) for failing to notify the NRC, within 60 days, that no principal activities under the license had been conducted for a period of 24 months. Specifically, the licensee ceased principal activities in February 2009 and did not notify the NRC until August 12, 2011, a period exceeding 24 months plus 60 days.

On August 12, 2011, the licensee sent NRC a document requesting termination of the license. On September 12, 2011, the NRC held an exit meeting with licensee management regarding the NRC inspection findings.

The NRC MCID Branch is currently reviewing the licensee's evaluation of decommissioning to determine whether the site can be released for unrestricted access pursuant to 10 CFR 20.1402.

5. PARTIAL LIST OF PERSONNEL CONTACTED:

Kevin Gara – Director of Safety, Health and Environmental Protection
Thomas Schumacher – Radiation Safety Officer
Katie Franssen – Health and Safety Professional

Individuals telephonically present at exit meeting on September 12, 2011

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