

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Eurofins Scientific 15 Research Park Drive St. Charles, MO 63304</p> <p>REPORT NUMBER(S) 2019001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-38742</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-35149-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>02/05/19, with in-office review through 02/18/19</p>

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Ryan Craffey	<i>Ryan Craffey</i>	02/25/2019
BRANCH CHIEF	Aaron McCraw	<i>Robert D. Attone, Jr. for ATM</i>	3/15/19

**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Eurofins Scientific 15 Research Park Drive St. Charles, MO 63304  REPORT NUMBER(S) 2019001	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
---	---

3. DOCKET NUMBER(S)  030-38742	4. LICENSE NUMBER(S)  24-35149-01	5. DATE(S) OF INSPECTION  02/05/19, with in-office review through 02/18/19
--------------------------------------	---	--

6. INSPECTION PROCEDURES USED  87125	7. INSPECTION FOCUS AREAS  All
--	--------------------------------------

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03620	2. PRIORITY  5	3. LICENSEE CONTACT  James Hatten - RSO	4. TELEPHONE NUMBER  (800) 383-0468
---------------------------------	----------------------	---	---

- Main Office Inspection      Next Inspection Date: 02/05/2024
- Field Office Inspection    6 Research Park Drive, St. Charles, MO
- Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was an unannounced routine inspection of a bioanalytical services provider authorized to use radioactive material for research and development at two adjacent facilities in St. Charles, Missouri. At the time of the inspection, the licensee routinely used I-125 radioimmunoassay kits for sample testing at the 15 Research Park Drive facility (Building 15), and a variety of radiolabeled compounds containing I-125, C-14, H-3 and S-35 for radioligand binding and transporter assays at the 6 Research Park Drive facility (Building 6). The licensee retained the services of a health physics consultant to serve as RSO, who performed annual program audits and radiation safety training.

PERFORMANCE OBSERVATIONS: The inspector toured both facilities in St. Charles to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys and found no evidence of residual contamination or exposures to personnel in excess of regulatory limits. The inspector observed demonstrations of package receipt, utilization of material including accountability and contamination control practices, decay-in-storage waste handling, and area surveys. The inspector interviewed several authorized users and reviewed a selection of records including survey results, utilization records, and annual audits.

The inspector also reviewed a discrepancy identified by the licensee in its materials authorizations. About a month prior to the inspection, the staff realized that the ongoing use of I-125 in microcurie quantities at Building 6 was contrary to LC 10, which excluded authorization for I-125 from this location of use. The licensee had originally requested to add Building 6 in correspondence dated 08/22/17, stating that "the uses within this building will be the same as currently used in Building 15." At the time, I-125 was used at Building 15 in bound, non-volatile form. However, the license was subsequently amended to authorize Building 6, but to exclude the use of I-125 there. The licensee stated during the inspection that had not intended for such an outcome. The inspector confirmed that (1) the licensee used I-125 in the same manner as it did in Building 15, and (2) neither the licensee's original request nor the additional correspondence dated 09/29/17 requested such an exclusion. The inspector therefore determined that any potential violation of LC 10 would be administrative in nature and of minor safety significance. The licensee submitted a request to correct this discrepancy on 02/07/19; the NRC received this request on 02/12/19. No other violations of NRC requirements were identified as a result of this inspection.