NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Eurofins BioPharma Product Testing Columbia, Inc. 7200 East ABC Ln. Columbia, MO 65202 **Report Number(s)** 2022001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-05154	24-13365-01	June 22, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Jason Draper, Health Physicist	Jason D. Draper Digitally signed by Jason D. Draper Date: 2022.07.15 13:50:44 -05'00'
BRANCH CHIEF		Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.07.20 05:49:16 -05'00'

Add Continuation Page

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Eurofins BioPharma Columbia	030-05154	24-13365-01

4. Report Number(s):	5. Date(s) of Inspection:
2022001	June 22, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Draper	03610	3	IP 87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Mark Gilliland, RSO	MarkGilliland@eurofinsus.com	(573) 777-6242

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☑ Announced	☐ Main Office ☑ Field Office	06/22/2022 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a biopharmaceutical research and development company authorized to operate a Type A broad scope program. While the licensee was authorized for a wide variety of radioisotopes at two locations in Columbia, at the time of the inspection the licensee almost exclusively used millicurie quantities of C-14 and occasional H-3, primarily for research involving radiolabeling of pharmaceutical compounds for customers, and only actively performed these activities at the ABC Drive location. Radioactive material and waste was stored at both locations. The licensee had one active permit with four "Class I" and three "Class II" authorized users. This licensee had a radiation safety committee that met quarterly and approved research studies, laboratories, and authorized users. The licensee radiation safety staff consisted of the RSO and an Environmental Health and Safety Administrator.

During the inspection, the inspector toured the licensee's facilities at the ABC Drive location including research labs, materials storage areas, waste processing areas, and former material use areas. The inspector observed the handling of C-14 licensed material by the permit supervisor and interviewed him regarding material handling, material storage, inventory control, and waste processing. The inspector also interviewed the RSO and EHS Administrator regarding material receipt procedures, waste processing procedures, routine surveys, bioassays, decommissioning of facilities, and training of staff. The inspector reviewed a selection of records including radiation safety committee minutes, authorized user training and approvals, bioassay records, survey records, material receipt and inventory records, waste records, and periodic program reviews. From these reviews, the inspector found the licensee to be operating in accordance with NRC requirements and radiation safety principles.

During the previous inspection (IR 2018001) a violation was cited for the licensee's failure to perform weekly contamination surveys of laboratory suites as required by the licensee's May 23, 2017, license application and License Condition 22.A. During this inspection, the inspector verified that the licensee amended its license to implement alternate survey criteria, allowing the licensee to perform surveys based on the frequency, amount, and type of licensed material used. The inspector also verified that the licensee performed these surveys in accordance with these alternate survey criteria. This violation is closed.

No violations of NRC requirements were identified as a result of this inspection.

From: Draper, Jason
To: markgilliland@eurofinsus.com
Subject: NRC 591M - Eurofins BioPharma
Date: Wednesday, July 20, 2022 8:23:00 AM
Attachments: NRC 591M - Eurofins BioPharma jdmk.pdf

Mark,

As we discussed following my inspection, attached is the inspection report for the routine NRC inspection that was performed at your facility in Columbia, Missouri, on June 22, 2022. Please review and keep this document for your records. There is no response required, though I would appreciate an email confirming that you have received the document. Let me know if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Jason Draper
Health Physicist (Inspector)
NRC / Region III / DNMS / MIB
(630) 829-9839
jason.draper@nrc.gov