

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Charles River Laboratories, Inc.  
54943 N Main Street  
Mattawan, MI 49071

REPORT NUMBER(S) 2021001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38755

4. LICENSE NUMBER(S)

21-11315-04

5. DATE(S) OF INSPECTION

December 2 &amp; 3, 2021

## 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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2021.12.15 15:37:34 -06'00'</small>	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.12.29 10:54:53 -06'00'</small>	



## Materials Inspection Record

1. Licensee Name: Charles River Laboratories, Inc.		2. Docket Number(s): 030-38755		3. License Number(s) 21-11315-04	
4. Report Number(s): 2021001			5. Date(s) of Inspection: December 2 & 3, 2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 03210		8. Priority: 2	9. Inspection Guidance Used: 87126
10. Licensee Contact Name(s): Aura Kozminske- RSO		11. Licensee E-mail Address: Aura.kozminske@crl.com		12. Licensee Telephone Number(s): Office: (269) 598-8010 Cell: (269) 250-2136	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 12/02/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

## 16. Scope and Observations:

This was an announced routine inspection of a drug development research organization authorized for radionuclide production using a Siemens RDS Eclipse cyclotron at its campus in Mattawan, Michigan. The licensee owned, maintained, staffed, and operated the cyclotron. The cyclotron manufacturer performed the majority of service on the unit when required. At the time of the inspection, the licensee produced carbon-11 and fluorine-18 for use in animal imaging studies conducted on the premises under a research and development license (030-08546, 21-11315-02).

## PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the facilities, interviews with select licensee personnel, a review of select records, an observation of security of the materials, and independent measurements. The inspector toured the facilities where the cyclotron were located to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector was unable to observe any cyclotron operations, as the production was done earlier in the morning. However, the inspector had the licensee's staff demonstrate the implementation of procedures for cyclotron operations, byproduct materials productions, hot cell operations, QA process, maintenance, area surveys, and waste handling. The inspector observed that the licensee staff was wearing the proper PPE (lab coats, gloves, booties, and safety glasses), assigned dosimetry (finger and body) badges, and frisked their hands and feet before exiting the cyclotron operation facility. Through these demonstrations, observations, and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records relating to the use of the cyclotron, area surveys, training documentation, annual audits, exhaust system certificate, and instrument calibration. The inspector reviewed dosimetry records for 2019 through December 31, 2020, indicating the maximum annual dose to be 286 mrem - DDE, and 11,638 mrem - SDE. The inspector performed independent radiation measurements and found no exposures distinguishable from background.

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