NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Charles River Laboratories, Inc. 54943 N Main Street Mattawan, MI 49071 REPORT NUMBER(S) 2021001	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
030-08546	21-11315-02	December 2 & 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 violations(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 Digitally signed by Zahid M. Sulaiman Date: 2021.12.15 15:39:57 -06'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.12.29 10:46:58 -06'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Charles River Laboratories, Inc.	030-08546	21-11315-02

4. Report Number(s):	5. Date(s) of Inspection:
2021001	December 2 & 3, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	03611	5	87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Aura Kozminske- RSO	Aura.kozminske@crl.com	Office: (269) 598-8010 Cell: (269) 250-2136

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☐ Announced	☑ Main Office ☐ Field Office	12/02/2026 ☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an unannounced routine inspection of a drug development research company authorized to use byproduct materials for pre-clinical and biomedical research and development, including the short-lived radioactive compounds from an on-site cyclotron facility (produced under research production docket number 030-38755), at its campus in Mattawan, Michigan. At the time of inspection, the licensee used materials primarily for animal studies in various stages of the drug development process, in experimental surgical techniques, and medical device testing. The licensee used the materials for uptake and molecular imaging studies in its ADME department, Molecular Imaging department, and in several other research and development areas. The licensee was staffed with five authorized users, 18 technicians, and approximately 425 employees considered as radiation workers.

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 laboratories and imaging studies facilities to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector had the staff demonstrate/discuss byproduct materials ordering, receiving, and check-in procedures, master inventory list and tracking of licensed materials, security of materials, program audits, laboratory surveys, wipe tests, and waste handling. The staff described the radioactive waste collection process from the labs and transport to waste storage facility, and radioactive waste disposal to an authorized vendor. The inspector observed an imaging study that was in-progress, interviewed several radiation workers to discuss the implementation of licensee procedures and practices for materials use, waste handling, area surveys, personnel monitoring, and training. The inspector discussed with the technicians about the contamination and spill incident events and reviewed the licensee's response procedures and surveys data; no issues were noted. Through these demonstration, observation, and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector performed independent radiation measurements and found no exposures distinguishable from background.

The inspector reviewed a selection of records: annual program audits, contamination and spill incident reports, sealed source inventory and leak tests, materials ordering, radioactive materials inventory, annual radiation worker refresher training, package receipt, vent hood airflow check, instrument calibration, waste shipment, and annual Air Comply report (2020). 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.

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