

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Zoetis LLC 333 Portage Street Kalamazoo, MI 49007 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) 030-04781		4. LICENSE NUMBER(S) 21-00182-03		5. DATE(S) OF INSPECTION December 1 & 2, 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 16:11:30 -06'00'</small>	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.12.29 10:32:07 -06'00'</small>	



Materials Inspection Record

1. Licensee Name: Zoetis LLC		2. Docket Number(s): 030-04781		3. License Number(s) 21-00182-03	
4. Report Number(s): 2021001			5. Date(s) of Inspection: December 1 & 2, 2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 03610		8. Priority: 3	9. Inspection Guidance Used: 87126
10. Licensee Contact Name(s): John Stuedemann- RSO		11. Licensee E-mail Address: John.m.stuedemann@zoetis.com		12. Licensee Telephone Number(s): (269) 720 - 8067	
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 checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 12/01/2024 <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 unannounced, routine inspection of an animal health and vaccination research corporation, authorized to use a variety of byproduct material for pharmaceutical research and development including animal studies at its main facility in Kalamazoo, Michigan, and at its satellite facility in Richland, Michigan. At the time of the inspection, the licensee had five authorized users, seven laboratories, and approximately 44 trained radiation workers working with the radioactive materials. The licensee primarily used H-3 and C-14. The licensee no longer conducted animal studies under the license; instead, it received tissue samples containing radioactive material from a contractor to performed the studies.

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 in Kalamazoo and the storage freezer at the Richland, Michigan 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, approval process of principal investigators and material users, 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, liquid waste sewer disposal, and radioactive waste disposal to an authorized vendor. The inspector toured three laboratories authorized for radioactive materials use and verified selected materials on the inventory. The inspector also toured the licensee's waste storage facility and receiving dock, where the inspectors interviewed select shipping and receiving staff on the licensee's procedures for receipt of radioactive material. Through these discussions and demonstrations, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and exposure control.

The inspector reviewed a selection of records: annual program audits, radiation safety committee minutes, sealed source inventory and leak tests, materials ordering, radioactive materials inventory, annual radiation worker refresher training, package receipt, vent hood airflow check, instrument calibration, radiation safety and DOT Hazmat training, liquid waste sanitary sewer release reports, waste shipment, and annual Air Comply report (2020). The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

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