

(07-2012)*
10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: US Department of Health and Human Services Food and Drug Administration 109 Holton Street Winchester, MA 01890-1197 REPORT NUMBER(S) 2019-001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region I, 2100 Renaissance Blvd, Suite 100 King of Prussia, Pennsylvania 19406-2713	
3. DOCKET NUMBER(S) 030-04675	4. LICENSE NUMBER(S) 20-08361-01	5. DATE(S) OF INSPECTION July 18, 2019	

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:

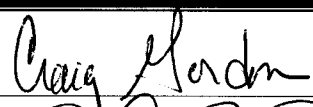

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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) and corrective action(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 the 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	Craig Gordon, Sr. Health Physicist		7/24/19
BRANCH CHIEF	Anne DeFrancisco, Acting Chief, CIRDA		8/9/19

*NRC FORM 591M PART 1 (07-2012) (RI Rev. 09/12/2013) G:\WBL Documents\WBL Inspection Records\R20-08361-01.2019-001.591M-Part1.doc

SUNSI Review Completed By: / RA / CGordon



Public



Non-Sensitive

This document becomes an NRC Official Agency Record once it is signed by the Branch Chief