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
Zevacor Molecular 14365 Bergen Blvd. Noblesville, IN 46060 REPORT NUMBER(S) 2016001	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
030-38841, 030-38903	13-35179-02, 13-35179-03	October 27 , 2016

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	Luis Nieves Folch		7/25/2017
BRANCH CHIEF	Aaron T. McCraw		8/3/17

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03620	5	John Zehner, R.Ph, RSO	(317) 578-1251

☑ Main Office Inspection Next Inspection Date: October 27, 2021

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an initial, announced inspection of a research and development licensee that possessed a cyclotron in Noblesville, IN. The licensee operated Monday to Friday. The licensee was in the pre-production of radiopharmaceuticals for testing, validation, and qualification of FDA-regulated drug products stage and planned to start full production next year after amending their license. So far the licensee has produced two test batches of strontium-82. The licensee was using an external company for the transport of license material.

Performance Observation
The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the handling of the material inside a hot cell. The licensee's staff demonstrated the implementation of procedures for air effluent monitoring, shipping material, spills, waste handling, and bioassay for personnel. Through these observations, demonstrations, and other 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, including internal and external audits, air effluent monitoring reports, survey meter calibration certificates, hazmat training records, bioassay results, and dosimetry reports, which indicated annual whole-body and extremity doses below regulatory limits.

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