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
Zervacor Pharma, Inc d/b/a Zervacor 21000 Atlantic Boulevard Suite 730 Dulles, VA 20166 REPORT NUMBER(S) 2017001	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
030-38113	45-25221-05	April 11 , 2017

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		4/11/17
BRANCH CHIEF	Aaron T. McCraw		4/26/17

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
87136	03.01-03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03210	2	Todd Heiskell, RSO	(816) 801-8544

☑ Main Office Inspection Next Inspection Date: April 11, 2019

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a cyclotron/pharmacy located in Kansas City, Missouri. This inspection focused on the cyclotron. The licensee employed three pharmacists and six pharmacy technicians; the shipping of the material was subcontracted. The licensee dispensed approximately 90 doses daily to customers as far as Iowa and South Dakota. The cyclotron operated form 12:00pm to 7:00am on weekdays. Their runs ran at 12:00pm, 2:30am, 4:00am, 6:45am, and 7:00am with limited hours on weekends for the production of F-18 and sodium floride. The licensee performed annual corporate audits to ensure compliance with regulatory requirements.

Performance Observations

The inspector observed transfer of materials from the cyclotron to chemistry, QC sampling and analysis, dose preparation and packaging, shipping package preparation and surveys, preparation of shipping papers and labels, transfer of packages to couriers, and handling of returned packages. Licensee personnel demonstrated and described spill procedures, cyclotron maintenance, target preparation and maintenance, stack and effluent monitoring, daily surveys, waste handling and disposal, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee staff indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements that indicated results consistent with licensee survey records and postings.

The inspector reviewed a selection of records, including internal audits, dose calibrator constancy, dose calibrator linearity, dose calibrator accuracy, survey meter calibration certificates, hazmat training records, well counter constancy, area surveys, and dosimetry reports.

For future inspections under this license, the inspector should contact Region I to ask if they would like an inspection of the pharmacy license, 45-25221-0lMD, to be performed concurrently.

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