



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

September 10, 2018

Chandra K. Sacheti, M.D.
Chandra K. Sacheti, M.D., LLC
561 Talcottville Road
Vernon, CT 06066

**SUBJECT: CHANDRA K. SACHETI, M.D., LLC - NRC INSPECTION NO.
03036145/2018001 AND NOTICE OF VIOLATION**

Dear Dr. Sacheti:

This letter refers to the inspection conducted on May 31, June 27, and August 20, 2018, at your facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The findings of the inspection were discussed with you at the Exit Meeting held on August 20, 2018.

Based on the results of this inspection, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Robert Gallagher of my staff at (610) 337-5182 or via electronic mail at Robert.gallagher@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03036145
License No. 06-30781-01

Enclosure:
Notice of Violation

cc w/Encl: State of Connecticut

CHANDRA K. SACHETI, M.D., LLC - NRC INSPECTION NO. 03036145/2018001 AND
NOTICE OF VIOLATION DATED __9/10/18_____

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DATE	9/10/18		9/10/18					

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NOTICE OF VIOLATION

Chandra K. Sacheti, M.D., LLC
Vernon, CT

Docket No. 03036145
License No. 06-30781-01

During an NRC inspection conducted on May 31, June 27, and August 20, 2018, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.67(b)(2) requires a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Contrary to the above, Chandra K. Sacheti, M.D., LLC did not test the sealed sources in their possession for leakage in accordance with 10 CFR 35.67(b)(2). Specifically, leak tests of sealed sources were not performed between October 23, 2015 and June 6, 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

- B. 10 CFR 35.67(g) requires a licensee in possession of sealed sources conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, Chandra K. Sacheti, M.D., LLC did not conduct a semi-annual physical inventory of sealed sources in their possession in accordance with 10 CFR 35.67(g). Specifically, inventories of sealed sources were not performed between October 23, 2015 and June 6, 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

- C. 10 CFR 35.60(b) requires a licensee to calibrate instrumentation used to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject in accordance nationally recognized standards or the manufacturer's instruction.

Contrary to the above, Chandra K. Sacheti, M.D., LLC did not calibrate instrumentation used to measure the activity of unsealed byproduct material before it is administered to each patient in accordance with 10 CFR 35.60(b). Specifically, the instrumentation used to measure the activity of unsealed byproduct material before administration was not calibrated for accuracy, linearity or geometry between October 23, 2015 and June 6, 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

- D. 10 CFR 35.61(a) requires a licensee to calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually and following repair.

Contrary to the above, Chandra K. Sacheti, M.D., LLC did not calibrate survey instruments used to show compliance with this part and 10 CFR Part 20 in accordance with 10 CFR 35.61(a). Specifically, Ludlum Model 14-C, serial number 197853 was not

calibrated between September 2015 and April 2017 and again not calibrated between April 2017 and June 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

- E. 10.CFR 20.1101(c) requires, in part, that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, Chandra K. Sacheti, M.D., LLC did not periodically (at least annually) review the radiation protection program content and implementation. Specifically, no review of the radiation protection program content and implementation was performed between October 2015 and June 2018.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, Chandra K. Sacheti, M.D., LLC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 10th day of September 2018