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CHANDRA K. SACHETI, M.D., LLC

562 Talcottville, Vernon, CT 06066 Tel. 860-871-2016

To: Donna M. Janda, Chief
USNRC Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Sept. 26, 2018

RE: Reply to a Notice of Violation.

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

Dear Mrs. Janda:

The following is submitted in response to the inspections of our facility and a subsequent notice of violation arising from those efforts by your staff.

- A. 10 CFR 35.67(b)(2): Failure to perform leak tests on sealed sources between 10/23/15 to 6/06/18.
 - 1. Reason: Poor management of our program by myself and the technologist as we were operating without a physicist for the imaging service to this office.
 - 2. Corrective steps taken & results achieved: We have hired a very experienced physicist to assist us in maintaining compliance with our program.
 - 3. Corrective steps taken to avoid further violations: The physicist, Peter J. Mas, MS, DABMP, has implemented a QA schedule that must be followed for our continued compliance. He will audit the facility and evaluate our progress on a quarterly basis, if not more often.
 - Date to achieve full compliance: Presently in compliance. Mr. Mas will review our program and the continued adherence/outcomes from our corrective actions through 12/31/18.
- B. 10 CFR 35.67(g): Failure to perform semi-annual physical inventory of sealed sources between 10/23/15 to 6/06/18.
 - 1. Reason: Poor management of our program by myself and the technologist as we were operating without a physicist for the imaging service to this office.
 - Corrective steps taken & results achieved: We have hired a very experienced physicist to assist us in maintaining compliance with our program.
 - 3. Corrective steps taken to avoid further violations: The physicist, Peter J. Mas, MS, DABMP, has implemented a QA schedule that must be followed for our continued compliance. He will audit the facility and evaluate our progress on a quarterly basis, if not more often.

- Date to achieve full compliance: Presently in compliance. Mr. Mas will review our program and the continued adherence/outcomes from our corrective actions through 12/31/18.
- C. 10 CFR 35.60(b): Failure to calibrate instrumentation used to measure the activity of unsealed byproduct material that is administered to a patient between 10/23/15 to 6/06/18.
 - 1. Reason: Poor management of our program by myself and the technologist as we were operating without a physicist for the imaging service to this office.
 - 2. Corrective steps taken & results achieved: We have hired a very experienced physicist to assist us in maintaining compliance with our program.
 - 3. Corrective steps taken to avoid further violations: The physicist, Peter J. Mas, MS, DABMP, has implemented a QA schedule that must be followed for our continued compliance. He will audit the facility and evaluate our progress on a quarterly basis, if not more often.
 - Date to achieve full compliance: Presently in compliance. Mr. Mas will review our program and the continued adherence/outcomes from our corrective actions through 12/31/18.
- D. 10 CFR 35.61(a): Failure to calibrate survey instruments used to show compliance with this part and 10 CFR 20 between September 2015 to June 2018.
 - 1. Reason: Poor management of our program by myself and the technologist as we were operating without a physicist for the imaging service to this office.
 - 2. Corrective steps taken & results achieved: We have hired a very experienced physicist to assist us in maintaining compliance with our program.
 - 3. Corrective steps taken to avoid further violations: The physicist, Peter J. Mas, MS, DABMP, has implemented a QA schedule that must be followed for our continued compliance. He will audit the facility and evaluate our progress on a quarterly basis, if not more often.
 - Date to achieve full compliance: Presently in compliance. Mr. Mas will review our program and the continued adherence/outcomes from our corrective actions through 12/31/18.
- E. 10 CFR 20.1101(c): Failure to periodically (at least annually) review the radiation protection program content and implementation between October 2015 to June 2018.
 - 1. Reason: Poor management of our program by myself and the technologist as we were operating without a physicist for the imaging service to this office.
 - 2. Corrective steps taken & results achieved: We have hired a very experienced physicist to assist us in maintaining compliance with our program.
 - 3. Corrective steps taken to avoid further violations: The physicist, Peter J. Mas. MS.

- DABMP, has implemented a QA schedule that must be followed for our continued compliance. He will audit the facility and evaluate our progress on a quarterly basis, if not more often.
- 4. Date to achieve full compliance: Presently in compliance. Mr. Mas will review our program and the continued adherence/outcomes from our corrective actions through 12/31/18. He will document a 2018 Radiation Protection Program Review for the office records.

In summary, we have implemented specific changes to ensure that, going forward, our program operates more reliably and maintains compliance with the regulations and the commitments to this material license.

Respectfully submitted,

Chandra K. Sacheti, MD

Chambra & Sacheli

cc: P. Mas, MS