April 7, 2011

CAL-3-08-004

Mr. Gary Williams, Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: CLOSEOUT OF CONFIRMATORY ACTION LETTER 3-08-004, DEPARTMENT OF VETERANS AFFAIRS

Dear Mr. Williams:

On October 14, 2008, the U.S. Nuclear Regulatory Commission (NRC) issued a Confirmatory Action Letter (CAL), Number 3-08-004, to the Department of Veterans Affairs (DVA) to document your commitment to implement both short and long term corrective actions to resolve issues associated with the prostate brachytherapy programs which resulted in numerous medical events at DVA hospitals. At the time the CAL was issued, the DVA had identified medical events at the following Veterans Affairs (VA) hospitals: the VA Medical Center Philadelphia (PVAMC) reported 92 medical events; the G. V. (Sonny) Montgomery VA Medical Center Jackson reported 8 medical events; the VA Medical Center Cincinnati reported 6 medical events; and the VA Medical Center Washington, D.C. reported three medical events.

The CAL specifically required you to: (1) conduct reactive inspections of all the active prostate brachytherapy programs and provide the results of these inspections to the NRC; (2) develop and implement standardized procedures for conducting prostate brachytherapy treatments which at a minimum included: training on medical events (what constitutes a medical event, how to identify a medical event, the criteria the DVA has established to declare medical events involving permanent prostate brachytherapy, and the reporting requirements), methods to verify needle placement in the prostate prior to seed implantation, preparation of written directives, pre-treatment and post-treatment planning, and dose verification; (3) correct incompatible data transmission problems; (4) identify root causes and corrective actions to prevent recurrence; (5) immediately suspend any prostate brachytherapy program where medical events are identified for 20 percent or more of the prostate treatments performed and develop enhanced criteria for suspending prostate brachytherapy programs; (6) conduct an inspection prior to restart of a suspended prostate brachytherapy program to confirm implementation of all corrective actions and provide notification to the NRC; and (7) before start-up of any new prostate brachytherapy programs at VA facilities, the NHPP would conduct an inspection to confirm that the standardized prostate brachytherapy procedures have been implemented, the individuals involved in the treatments have completed training (on medical events, methods to verify needle placement in the prostate prior to seed implantation, preparation of written directives, pre-treatment and post-treatment planning, and dose verification), and provide notification to the NRC. The DVA completed Items 1 through 7 of the CAL as required.

Additionally, the DVA established the criteria required in Item 7 of the CAL for start-up of a new program; however, the DVA has not established a new prostate brachytherapy program since the CAL was issued.

The NRC staff reviewed your implementation of the CAL commitments during reactive inspections at the thirteen VA facilities with active prostate brachytherapy programs. These inspections were conducted between October 8, 2008, and April 24, 2009, at the following permitted VA facilities: (1) G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; (2) VA Medical Center, Cincinnati, Ohio; (3) VA Medical Center, Minneapolis, Minnesota; (4) VA Puget Sound Healthcare System, Seattle, Washington; (5) VA Sierra Nevada Healthcare System, Reno, Nevada; (6) Samuel S. Stratton VA Medical Center, Albany, New York; (7) VA New York Harbor Healthcare System, Brooklyn, New York; (8) VA Boston Healthcare System, Boston, Massachusetts; (9) VA Medical Center, Washington, District of Columbia; (10) VA Greater Los Angeles Healthcare System, Los Angeles, California; (11) VA Medical Center, San Francisco, California; (12) VA Medical Center, Durham, North Carolina; and (13) Hunter Holmes McGuire VA Medical Center, Richmond, Virginia. Our inspection included in-office review through April 22, 2010. The continued NRC in-office review included an assessment of your 15-day written reports for medical events reported at the VA Jackson, the VA Cincinnati, the VA Brooklyn, the VA Los Angeles, and the VA Durham facilities. Our in-office review also included a review of patient dose data for medical events reported at the VA Brooklyn, the VA Los Angeles and the VA Durham facilities, training records for numerous facilities, and patient treatment records for several facilities. The results of these inspections were provided to you in NRC Inspection Report No. 030-34325/2008-030(DNMS) dated May 24, 2010.

The NRC staff further evaluated and confirmed implementation of CAL commitments and corrective actions during routine inspections conducted between June 9, 2010 and March 10, 2011, at the following VA facilities: G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; VA Medical Center, Cincinnati, Ohio; Philadelphia VA Medical Center, Philadelphia, Pennsylvania; VA Medical Center, Durham, North Carolina; Hunter Holmes McGuire VA Medical Center, Richmond, Virginia, VA; Boston Healthcare System, Boston, Massachusetts; VA New York Harbor Healthcare System, Brooklyn, New York; VA Greater Los Angeles Healthcare System, Los Angeles, California; VA Medical Center, San Francisco, California; VA Puget Sound Healthcare System, Seattle, Washington; and VA Sierra Nevada Healthcare System, Reno, Nevada. The results of these inspections were provided to you in NRC Inspection Report Nos. 030-34325/10-02(DNMS), 030-34325/10-01(DNMS), 030-34325/10-05(DNMS), 030-34325/11-03(DNMS), 030-34325/11-05(DNMS), 030-34325/11-11(DNMS), 030-34325/11-10(DNMS), 030-34325/11-15(DNMS), 030-34325/11-17(DNMS), 030-34325/11-18(DNMS), and 030-34325/11-16(DNMS), respectively. NRC staff also confirmed that the VA Medical Center, Minneapolis, Minnesota implemented the CAL commitments during an NRC accompaniment of an NHPP routine inspection at the VA Medical Center, Minneapolis, Minnesota, on December 21, 2010.

Based upon our review of the inspection results and the CAL commitments, the NRC has determined that you have effectively addressed each of the issues documented in the CAL. Therefore, we consider all commitments and associated actions documented in CAL 3-08-004 closed.

In accordance with Title 10 Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

Docket No. 030-34325
License No. 03-23853-01VA

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Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

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