



**Department of Veterans Affairs
Office of Inspector General**

Office of Healthcare Inspections

Report No. 13-00696-254

Healthcare Inspection

Follow-Up Assessment of Radiation Therapy VA Long Beach Healthcare System Long Beach, California

July 31, 2013

Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review in follow up of its March 2011 report on radiation therapy (RT) at the VA Long Beach Healthcare System (facility) in Long Beach, CA. OIG also assessed the validity of new allegations related to the quality of radiation treatments.

We conducted an unannounced inspection in December 2012 and an announced inspection in February 2013, observed the practices of radiation therapists, and examined departmental electronic and paper records that are accessible only onsite.

We found that prior to March 2011 the facility had no written policy for procedures to be followed when shifts in the field of delivered RT occurred. For three prostate cancer patients treated in 2009 and 2010, therapists did not obtain images following shift corrections. However, we were able to determine that appropriate corrections occurred and that, despite shifts, all patients received full treatment to tumor containing tissue. Additionally, there was no evidence of complications attributable to errors in delivery of radiation therapy.

We also found that a patient treated in 2010 for vocal cord cancer had transient skin abnormalities resulting from misdirection of the radiation beam. This problem was identified and corrected after 10 treatments, no long-term adverse consequences resulted from the initial misdirection of the radiation beam, and radiation was consistently delivered to the target lesion. For an additional 27 patients who were treated in 2012 and whose care we evaluated, we found that radiation treatment was appropriate but that in three cases treatment was delayed.

We found that documentation of patient care in the electronic health record remained deficient, which could potentially compromise overall patient care. This deficiency had been cited in a prior OIG report and in two accreditation surveys.

We found improvements in quality management, but also found that the reporting of adverse events did not occur as specified in the facility's action plan in response to the 2011 OIG report. We also found that the facility was unaware of a complication that was managed at a referring facility five months after completion of radiation treatment.

We recommended that the Under Secretary for Health ensure that repeated deficiencies in the documentation of patient care are addressed and do not persist. We also recommended that the Veterans Integrated Service Network (VISN) Director ensure that complications of radiation therapy that are managed at referring facilities are reported to the facility where radiation therapy was provided. Finally, we recommended that the VISN Director require that the facility Director ensure that radiation therapists adhere to local policy when shifts in the field of delivered radiation occur, and that adverse events in the Radiation Oncology department are consistently reported to facility managers as specified in the facility's action plan in response to the 2011 OIG report.

Comments: The Under Secretary for Health, VISN, and facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes A through C, pages 10–17 for their comments.) We will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to follow up on our March 2011 report¹ on radiation therapy (RT) at the VA Long Beach Healthcare System (facility) in Long Beach, CA. OIG also assessed the validity of new allegations related to the quality of radiation treatments, including allegations about the care provided for patients described in the 2011 report.

The objectives of this follow-up review were to determine whether:

- RT patients are receiving appropriate treatment.
- The radiation oncology (RO) department and the facility have an effective quality management (QM) program.
- Actions were completed in response to recommendations in the 2011 report.

Background

The facility is a tertiary care medical center that provides medical, surgical, neurological, psychiatric, and rehabilitative services in Veterans Integrated System Network (VISN) 22. The facility has 231 hospital beds and 91 community living center (nursing home) beds and is affiliated with the University of California at Irvine, California State University at Long Beach, and the University of Southern California.

In 2010, OIG received allegations that RO patients were receiving poor care because of incompetent radiation oncologists and a hostile working environment. We conducted a site visit in November 2010 and substantiated the allegation of poor care for 1 of the 10 patients reported and identified deficiencies in electronic health record (EHR) documentation for 9 of the 10 patients. We also substantiated that facility leaders were not aware of adverse patient outcomes in RT and found that actions were not taken to correct deficiencies identified in peer reviews. We did not substantiate the allegation that radiation oncologists lacked competence and we did not address the allegation of a hostile work environment. Following publication of the 2011 report, the OIG received additional allegations that detailed specific aspects of the care provided to individual patients.

RT, along with medical and surgical interventions, is one of the three primary approaches to cancer treatment. RT uses ionizing radiation to destroy or inhibit the growth of cancer tissue. To be delivered safely and effectively, RT requires effective communication among primary care physicians, medical oncologists, surgeons, and members of the RT treatment team. The RT treatment team includes radiation oncologists and therapists, dosimetrists, physicists, and nurses, and careful coordination is essential within this group.

In the documentation of RT care for individual patients, several elements are expected. These include the extent to which patients participate in planning for their care; details

¹ Healthcare Inspection – *Alleged Poor Quality of Care in Radiation Therapy, VA Long Beach Healthcare System, Long Beach, California*, Report No. 10-03861-119, March 9, 2011.

about the plan for and delivery of RT treatments; monitoring of response, side effects, and outcome; and the care anticipated following RT. At a minimum, documentation should include an initial consultation, a summary describing completed treatment, and a follow-up evaluation.²

In response to deficiencies identified by the OIG during its November 2010 site visit, the facility Director requested that a review be conducted by the National Director (ND) of the Veterans Health Administration (VHA) RO Program. In a December 2010 report, the NDRO noted that “multiple mandatory quality assurance procedures have not been performed by the medical physicist” and that similar deficiencies had been cited by the American College of Radiology (ACR) during its 2009 survey. The NDRO also stated that the “time from consult to treatment is typically three weeks, which is not acceptable.” The NDRO recommended that the facility immediately increase the number of medical physicists, radiation therapists, and administrative personnel.

The facility planned comprehensive actions to address all identified deficiencies:

- An external protected peer review of the care provided to Patient 1 in the 2011 OIG report was completed.
- The RT QM Committee (RTQMC) was developed to ensure that clinical care documentation and quality improvement activities comply with VHA and ACR guidelines.
- Daily audits are conducted to ensure that progress notes, treatment summaries, and documentation of radiation dose and treatment modifications are completed.
- Documentation discrepancies are addressed in weekly chart round meetings.
- EHR aggregate data is reported to the RTQMC monthly.
- The RTQMC provides a summary of all adverse clinical outcomes to the Medical executive Committee (MEC) quarterly.
- A summary of all adverse clinical outcomes is provided to the facility Executive Leadership and Quality Board (ELQB).

In a June 2012 follow-up report, the NDRO noted that although several components of the action plan had been implemented, there were recommendations in medical physics that remained to be completed. The report recommended that planned new modalities of radiation treatment be deferred until policies were developed and machine quality assurance equipment was purchased.

The facility underwent an accreditation review by the ACR on November 30, 2012. In a report dated January 25, 2013, the ACR described multiple deficiencies and deferred accreditation.

ACR findings included deficiencies in physics quality control and documentation of treatment planning and patient evaluations during and after completion of treatment. The report stated that the use of “three separate documentation systems is inefficient and could lead to mistakes,” and that this issue “was discussed in the 2009 report.” The

² American College of Radiology. *Practice Guideline for Communication: Radiation Oncology*, rev. 2009. http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Comm_Radiation_Oncology.pdf. Accessed May 8, 2013.

report also mentioned that it was unclear “how physician peer review was being conducted.”

Scope and Methodology

We conducted an unannounced inspection December 10–11, 2012, at which time we learned that ACR surveyors had been onsite during the prior week. We observed the practices of radiation therapists on December 10. We also evaluated the care provided to selected RT patients July–September 2012; patient EHRs were chosen to include a variety of cases, such as common and less common diagnoses and conditions associated with an increased risk of complications. For the patients scheduled for treatment December 10–11, 2012, we examined EHRs in addition to departmental electronic and paper records.

We observed selected RO departmental operations and interviewed facility managers, clinical care providers, and RT staff. We also reviewed QM reports; VHA, facility, and department policies and procedures; committee meeting minutes; and other pertinent documents. We evaluated the credentialing and privileging and training records of the radiation oncologists and corresponding records for the radiation therapists. To assess compliance with required documentation, we also reviewed RT summary notes and follow-up notes for patients whose treatments were completed during August–October 2012.

Subsequent to our December site visit, we received specific allegations of poor care allegedly provided to four patients in 2009 and 2010. We conducted an announced inspection on February 11, 2013, to examine records available only onsite.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Issue 1: Quality of Care

a. Patients Alleged to Have Received Substandard RT

Four patients were alleged by a complainant to have received substandard RT. We evaluated care for three of the patients as part of the 2011 OIG review. We re-assessed management of these patients in light of new allegations regarding specific aspects of RT. The fourth patient was identified following publication of the 2011 review.

We found that prior to March 2011 the facility had no written policy for procedures to be followed when shifts in the field of delivered RT occurred. For three prostate cancer patients treated in 2009 and 2010, therapists did not obtain images following shift corrections. However, we were able to determine that appropriate corrections occurred and that all patients received full treatment to tumor containing tissue. Additionally, there was no evidence of complications attributable to errors in delivery of radiation therapy.

1. A man in his 60s was treated with intensity modulated RT (IMRT) for prostate cancer in 2009. A progress note summarizing the treatment was signed by a radiation oncologist 15 weeks after completion of RT. When the patient was evaluated 6 weeks after completion of treatment, he reported mild bowel and bladder symptoms. As of May 2013, the patient was being seen at the facility for routine outpatient care.

2. A man in his 70s was treated with IMRT for prostate cancer in 2009. A progress note summarizing the treatment was signed by a radiation oncologist 7 weeks after completion of RT. The patient was seen 7 weeks after completion of treatment; at that time, he reported persistent nocturia. Approximately 8 months after completion of treatment, he developed hemorrhagic cystitis and was treated with hyperbaric oxygen. He subsequently had transient proctitis. In April 2013, the patient was seen at the facility for follow-up evaluation by a radiation oncologist; at that time, he had no urinary or gastrointestinal symptoms.

3. A man in his 70s was treated with IMRT for prostate cancer in 2009 and 2010. A progress note summarizing the treatment was signed by a radiation oncologist 8 weeks after completion of RT. When he was evaluated 6 weeks after completion of treatment, he was noted to have persistent nocturia. Ten months after completion of treatment, he underwent hyperbaric oxygen therapy for proctitis. During a follow-up evaluation by a radiation oncologist in December 2012, he was noted to have no gastrointestinal symptoms. As of April 2013, he was being seen at the facility for routine outpatient care.

We also found that a patient (Patient 4) with vocal cord cancer had transient skin abnormalities resulting from misdirection of the radiation beam. This problem was identified and corrected after 10 treatments, no long-term adverse consequences

resulted from the initial misdirection of the radiation beam, and radiation was consistently delivered to the target lesion.

4. A man in his 50s was treated for vocal cord cancer after referral from another VA facility. After initiation of RT and delivery of 10 treatments, a physician wrote that the patient's neck had "slight hyperpigmentation, no desquamation, bilateral neck swelling/will monitor/hyperpigmentation...Need to review patient's treatment beams tomorrow at treatment." The treatment field size was subsequently reduced. A progress note summarizing the treatment was signed by a radiation oncologist 5 weeks after completion of RT. When the patient was evaluated 6 weeks after completion of treatment, he described no major problems; a note summarizing the patient's post-treatment course was signed by a radiation oncologist on the day of that visit. At the referring facility 10 weeks after completion of therapy, the patient was evaluated by an otolaryngologist, who noted "significant supraglottic and post arytenoid edema." The patient subsequently required placement of a tracheostomy. As of July 2012, the patient was being followed by a primary care provider for routine outpatient care.

Patients 1–3 underwent RT for prostate cancer in 2009 and 2010. Our review of treatment records revealed that for each of these patients, shifts of greater than 5 mm in the field of delivered radiation occurred. Sound practice and the local policy written in 2011 require that new images be obtained and shifts approved by the treating physician whenever shifts of this magnitude occur; however, this requirement was not met on 30 of 35 occasions when such shifts occurred.

Although new images were not consistently obtained following shift corrections, we determined that appropriate corrections occurred in almost all cases. Further, despite shifts, all patients received full treatment to tumor containing tissue. These patients had urinary and bowel complications that occur frequently in association with RT for prostate cancer, and we found no evidence to indicate that these were related to shifts.

Patient 3 also had transient skin symptoms associated with treatment. In the treatment of prostate cancer, the skin is necessarily exposed to radiation, and skin reactions are not uncommon. Although this patient had a planned radiation dose to the skin that may be considered somewhat higher than usual, his skin reaction may have occurred regardless of the specific treatment plan.

Patient 4 was treated for vocal cord cancer and had skin abnormalities indicating misdirection of the beam of radiation. This problem was identified and corrected after 10 treatments, and no long-term consequences were identified. Our review of treatment records indicated that radiation was consistently delivered to the target lesion. Airway complications that resulted in the need for tracheostomy occurred after treatment, but these were not attributable to errors in the delivery of RT.

b. Patients Treated July–September 2012

Of the 34 patients who received RT at the facility July–September 2012, we selected 11 patients for review; these patients ranged in age from 62 to 87 years (median, 70). These patients were treated for malignancies involving the head and neck (8), esophagus (1), lung (1), prostate (1), and knee (1); one patient had both head and neck and esophageal cancer.

Following initial consultation with the radiation oncologist, patients undergo simulation to establish the appropriate volumes of tissue to be treated, identify normal structures within or adjacent to this volume, and determine optimal positioning.³ Although no published guidance specifies a maximum acceptable time from consultation with a radiation oncologist to simulation or initiation of treatment, VHA's NDRO Program, has written that the "time from consult to treatment...should be less than two weeks." For the 11 patients whose EHRs we reviewed, the median time from simulation to initiation of treatment was 25 days (range, 17–85 days). For nine of these patients, delays were attributable in part to planned initiation of chemotherapy prior to RT, completion of required imaging studies and surgical procedures, or difficulties coordinating care with patients and referring facilities. In no case was there evidence of clinical harm associated with delays.

We noted incomplete or delayed documentation of care for all 11 patients whose EHRs we reviewed. However, we did not find substantial deficiencies in the planning or delivery of RT.

c. Patients Under Treatment December 10–11, 2012

The 16 patients scheduled for treatment December 10–11, 2012, had malignancies involving the prostate (5), lung (5), head and neck (2), esophagus (1), brain (1), pancreas (1), and stomach (1). We reviewed the EHRs of these 16 patients. We again noted deficiencies in the documentation of care, but found no substantial deficiencies in the planning or delivery of RT. In three cases, we noted a delay in the initiation of treatment, two of which were attributable in part to the need for a diagnostic procedure or chemotherapy. In no case was there evidence of clinical harm associated with delays.

Issue 2: Documentation of Care

We found that documentation in the EHR remained deficient. This deficiency had been cited in OIG's 2011 report and in the ACR's 2009 and 2012 accreditation surveys. Our onsite inspection of departmental electronic and paper records revealed appropriate delivery of RT except as noted above. However, documentation of patient evaluations during and after treatment was often delayed or absent, which could potentially compromise overall patient care.

³ http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Radiation_Oncology.pdf. Accessed May 13, 2013.

Three records of care provided in the RO department are maintained simultaneously. First, RT staff keep paper records, including details of daily treatment. Second, staff document treatment using proprietary software accessible only in the department; this component of documentation includes specific aspects of treatment planning. Finally, patient evaluations and treatment summaries are entered in the VA EHR.

The ACR *Practice Guideline for Communication: Radiation Oncology* specifies that timely and accurate communications through written reports are critical to quality patient care.⁴ Radiation oncologists are expected to record an evaluation of patients at least weekly during treatment, a detailed summary at the completion of treatment, and at least one follow-up assessment. The guideline states that this information “should be in the medical record shortly after the visit or the completion of treatment.”

We found that required documents in the EHR were absent or were completed late. For specific note types, we found the following:

- **On-Treatment Notes:** Radiation oncologists are expected to document weekly patient evaluations during treatment. For 3 of the 27 patients who were treated July–September 2012 or December 10–11, 2012 and whose EHRs we reviewed, we found instances of absent weekly treatment notes. We found no deficiencies in the documentation of on-treatment notes for the four patients whose EHRs we reviewed onsite in February 2013.
- **Summary Notes:** Completion of a progress note summarizing the course of therapy is expected soon after treatment completion. This information is an important component of each patient’s ongoing care and needs to be available to primary care providers and medical and surgical specialists. For 20 of the 37 patients whose treatment was completed August–October 2012, summary notes were completed more than 10 days after the last treatment. For all 37 patients, the median time from the date of last treatment to completion of summary notes was 15 days (range, 1–92 days).
- **Follow-Up Notes:** Although no published criteria specify when follow-up should occur after completion of treatment, accepted practice is for patients to be evaluated approximately 6 weeks after final treatment. Of the 37 patients described above, 31 were alive 8 weeks after completion of treatment. Of these 31 patients, 6 had no follow-up notes. For the remaining 25 patients, the median time from the date of last treatment to completion of follow-up notes was 35 days (range, 8–105 days).

Additionally, notes must be signed in order for other providers to view them in the EHRs. Unsigned notes are not available for review by other clinicians. At the time of our site visit in December 2012, one radiation oncologist had 36 (9 percent) of 383

⁴ ACR. *Practice Guideline for Communication: Radiation Oncology*, rev. 2009. http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Comm_Radiation_Oncology.pdf. Accessed May 8, 2013.

notes entered since July 1 unsigned more than 10 days following the date of patient encounter.

Issue 3: QM Activities

Following the 2010 OIG visit, the facility established the RTQMC, which met monthly or more frequently February–October 2011 and in February, March, May, and October 2012. Meeting minutes in 2011 reflected 95 percent or greater compliance with documentation requirements with intermittent deficiencies identified in daily EHR nurse audits, weekly chart rounds, and monthly chart reviews. Meeting minutes in 2012 again indicated substantial compliance with documentation requirements.

We found that the reporting of RO adverse events did not occur as specified in the facility's action plan in response to the 2011 OIG report. We found that summaries of adverse clinical outcomes were reported to the MEC semi-annually rather than quarterly as specified in the facility's action plan in response to the OIG 2011 report. In addition, facility staff stated that summaries of adverse clinical outcomes were not reported to the ELQB.

VHA policy requires that all adverse events be reported to the facility Patient Safety Manager (PSM).⁵ The Chief of QM, who supervises the PSM, informed us that no adverse events in RT were reported even though MEC summaries indicated that adverse events had occurred.

In order to ensure quality of care, radiation oncologists should be aware of complications that occur following completion of radiation treatment. For patient #4 described above, however, the facility was unaware of a complication that was managed at the referring facility five months after completion of radiation treatment.

During 2011 and 2012, the facility referred one RO case for peer review. We found that the peer review was completed as required by VHA policy.⁶

Issue 4: Credentialing, Privileging, and Training

We reviewed the credentialing and privileging folders, profiles, and training records of the radiation oncologists and found that they were in compliance with VHA policy.⁷ We also found that each of the radiation therapists had completed required training.

⁵ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

⁶ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

⁷ VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008.

Conclusions

We found that for three prostate cancer patients treated in 2009 and 2010, therapists did not follow accepted practice when shifts in the field of delivered radiation occurred. However, we were able to determine that appropriate corrections occurred and that, despite shifts, all patients received full treatment to tumor containing tissue. Additionally, there was no evidence of complications attributable to errors in delivery of radiation therapy.

We also found that a patient with vocal cord cancer had transient skin abnormalities resulting from misdirection of the radiation beam. This problem was identified and corrected after 10 treatments. No long-term adverse consequences resulted from the initial misdirection of the radiation beam, and radiation was consistently delivered to the target lesion.

For an additional 27 patients who were treated in 2012 and whose care we evaluated, we found that radiation treatment was appropriate but that in three cases treatment was delayed.

We found that documentation in the electronic health record remained deficient, which could potentially compromise overall patient care. This deficiency had been cited in a previous report and in accreditation surveys.

We also found that the facility was unaware of a complication that was managed at a referring facility five months after completion of radiation treatment.

Recommendations

1. We recommended that the Under Secretary for Health ensure that repeated deficiencies in the documentation of patient care are addressed and do not persist.
2. We recommended that the VISN Director ensure that complications of radiation therapy that are managed at referring facilities are reported to the facility where radiation therapy was provided.
3. We recommended that the VISN Director require that the facility Director ensure that radiation therapists adhere to local policy when shifts in the field of delivered radiation occur.
4. We recommended that the VISN Director require that the facility Director ensure that adverse events in the Radiation Oncology department are consistently reported to facility managers as specified in the facility's action plan in response to the 2011 OIG report.

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 8, 2013

From: Under Secretary for Health (10)

Subject: Healthcare Inspection – Follow-Up Assessment of Radiation Therapy, VA Long Beach Healthcare System, Long Beach, CA

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for providing me this opportunity to respond to the follow-up assessment of the VA Long Beach Healthcare System's (VALBHS) Radiation Therapy Program.

2. I have reviewed the draft report and concur with the report's recommendations. Attached are corrective action plans. In addition, please refer to the VISN 22 Network Director comments and the VALBHS Facility Director comments.

3. If you have any questions or need additional information, please contact Karen Rasmussen, Acting Director, Management Review Service at (202) 461-6643, or by e-mail at karen.rasmussen@va.gov, or Stan Johnson, Network Director, VISN 22 at (562) 826-5963.

(original signed by:)

Robert A. Petzel, M.D.

Attachment

**VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan**

**Office of Inspector General, Draft Report, Healthcare Inspection Follow-Up
Assessment of Radiation Therapy VA Long Beach Healthcare System Long
Beach, California (VAIQ 7373901)**

Date of Draft Report: June 4, 2013

Recommendations/ Actions	Status	Completion Date
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Recommendation 1: We recommend that the Under Secretary for Health ensure that repeated deficiencies in the documentation of patient care are addressed and do not persist.

VHA Comments

Concur

The VHA Under Secretary for Health remains committed to providing appropriate oversight to ensure that repeated documentation deficiencies are addressed and do not persist. Corrective actions have already been implemented by the VA Long Beach Healthcare System (VALBHS) Facility Director, with ongoing oversight by the VISN 22 Network Director. The Facility Director has established and implemented a more comprehensive monitoring and reporting system to ensure compliance with timely documentation of clinical care in the Radiation Oncology program. In addition, the VISN Director has charged the Network 22 Clinical Services Council, comprised of the VISN Chiefs of Staff and Nurse Executives, to oversee the process, with monthly reporting requirements until four consecutive months of 90 percent or greater compliance is demonstrated. Thereafter, reporting will be quarterly. Repeated failures by the VALBHS Radiation Oncology Chief to properly supervise and enforce documentation requirements, are being addressed.

In the interest of better understanding the nature of documentation delays, the Facility Interim Chief of Staff performed a more intensive record review. Compliance with weekly On-Treatment notes was 93 percent. Regarding timeliness of Follow-Up Notes, the OIG calculated the days based on the date of last treatment. However, the Facility calculated the days based on the actual date of the follow-up visit. The average number of lapsed days of documentation for this same group of patients was only 2 days.

To further strengthen and improve the integrity of the VALBHS Radiation Oncology program, a combination of programmatic structural and functional changes are underway. The Under Secretary for Health, the Network Director, the Facility Director, and the Facility Interim Chief of Staff have been engaged in continuous communication regarding challenges and opportunities. As a result, the Network Director and Facility Director have developed an aggressive plan to reorganize the program.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: July 8, 2013
From: Director, Desert Pacific Healthcare Network (10N22)
Subject: Healthcare Inspection – Follow-Up Assessment of Radiation Therapy, VA Long Beach Healthcare System, Long Beach, CA
To: Under Secretary for Health (10)

1. Thank you for providing me this opportunity to respond to the follow-up assessment of the VA Long Beach Healthcare System's (VALBHS) Radiation Therapy Program.
2. Please accept my response to Recommendation 2, outlined below. In addition, please refer to the VALBHS Facility Director comments in subsequent pages.
3. If you have any questions or need additional information, please contact me at (562) 826-5963.



Stan Johnson, MHA, FACHE

Comments to OIG's Report

The following comments from the VISN 22 Network Director are submitted in response to Recommendation 2:

OIG Recommendations

Recommendation 2. We recommended that the VISN Director ensure that complications of radiation therapy that are managed at referring facilities are reported to the facility where radiation therapy was provided.

Concur.

Target date for completion: July 30, 2013

Response: Although we are not aware of any regulations or policies that require facilities to report complications of radiation therapy to the facility that provided the therapy, we believe that this constitutes appropriate communication and practice; therefore, we concur with implementing this recommendation. The VISN Director has established and implemented a communication and reporting system to ensure that radiation complications identified by VISN 22 facilities are communicated to the facility that provided the radiation therapy. Patient Safety Officers (PSO) monitor Patient Event Reports to identify patients with suspected or actual evidence of radiation complications that may have occurred at another facility. The PSO immediately notifies the Chief of Staff (COS), who communicates the information to the COS at the facility where the radiation therapy was provided. In addition, the Network 22 Clinical Services Council agenda now includes mandatory monthly reporting by all facilities, including negative responses.

System Director Comments

**Department of
Veterans Affairs**

Memorandum

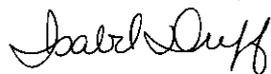
Date: July 12, 2013

From: Director, VA Long Beach Healthcare System (600/00)

Subject: Healthcare Inspection – Follow-Up Assessment of Radiation Therapy, VA Long Beach Healthcare System, Long Beach, CA

To: Director, Desert Pacific Healthcare Network (10N22)

1. Thank you for providing me this opportunity to respond to the follow-up assessment of the VA Long Beach Healthcare System's (VALBHS) Radiation Therapy Program.
2. Please accept my response to Recommendation 3 and 4, outlined below.
3. If you have any questions or need additional information, please contact me at (562) 826-5400.



Isabel Duff, MS

Comments to OIG's Report

The following Facility Director's comments are submitted in response to the Recommendations 3 and 4:

OIG Recommendation

Recommendation 3. We recommended that the VISN Director require that the facility Director ensure that radiation therapists adhere to local policy when shifts in the field of delivered radiation occur.

Concur

Target date for completion: Completed

Response: The patients reviewed in this hotline were from 2009 and 2010 and were prior to the OIG recommendation that a policy be developed and followed when shifts in the field of delivered radiation are indicated. In response to the OIG report in 2010, and although strong practices were in place, the facility issued a local policy defining clear procedures to be followed when shifts are performed. In addition, a Radiation Oncology Quality Management Committee was established in 2011, and was charged with the responsibility to monitor the appropriate response to field shifts in its daily reviews, with reporting explicitly included in the quarterly reports to the Medical Executive Council. The facility Director will continue to ensure radiation therapists follow local policy, as they have done since 2011.

Recommendation 4. We recommended that the VISN Director require that the facility Director ensure that adverse events in the Radiation Oncology department are consistently reported to facility managers as specified in the facility's action plan in response to the 2011 OIG report.

Concur

Target date for completion: Completed

Response: The OIG identified that summaries of adverse clinical outcomes reported through the Medical Executive Committee were not reported to the facility Patient Safety Officer or the Executive Leadership Quality Board.

In follow-up to the 2011 OIG report, a Radiation Oncology Quality Management Committee was established to oversee clinical care in the department. Regular reports of patients treated and adverse conditions were generated and were presented at the Medical Executive Council (MEC) meetings for five of the six quarters during this review period. The quarterly data that were not reported in December 2012 were reported in March 2013. Unfortunately, MEC reporting of these data to the Executive Leadership Quality Board (ELQB) was inconsistent.

Appendix C

It is important to note that there have been no occurrences of adverse events in the VALBHS Radiation Oncology department. The facility response used the terminology 'adverse clinical outcomes,' which included common and often expected complications that patients experience during the course of radiation therapy. These 'conditions' were monitored and reported, and served as a basis to make decisions about future treatments; however, they are not considered adverse events, based on the VHA definition in Handbook 1050.01. Therefore, they were not reported to the Patient Safety Officer.

The facility Director will ensure the Radiation Oncology Quality Management Committee clearly defines an adverse event, based on the VHA definition in Handbook 1050.01, as opposed to common and often expected complication that patients experience during the course of radiation therapy, and will also delineate this in future reports to MEC and ELQB. The facility Director will also ensure that the MEC submits these reports to the EQLB quarterly, until it is determined that quarterly reporting is no longer necessary.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Simonette Reyes, RN, Team Leader Jerome Herbers, MD Glen Pickens, RN, MHSM Jackeline Melendez, MPA, Program Support Assistant

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