POC ACCEPTABLE
YES X NO ☐
Reviewed By: Steve Lopez HFES (S. J. Spencer)
Name

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

Facility Notified
Date: 6/7/10
Time: 9 AM
Notified By: Name

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050121	A. BUILDING _____ B. WING _____	12/01/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Hanford Community Medical Center	450 GREENFIELD AVENUE, HANFORD, CA 93230 KINGS COUNTY

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	The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit: Complaint Intake Number: CA00204947 - Substantiated Representing the Department of Public Health: [redacted], HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1 (c): For purposes of this sections "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure had cause or is likely to cause serious injury or death to a patient. Deficiency Constitution Immediate Jeopardy Title 22 Div5 Art3-70223(b)(2) Surgical Service		AMMENDED JUNE 7, 2010, BY DIRECTOR OF ACCREDITATION. There was only one sharp utilized in the initial procedure on December 23, 2008, a guide wire that was placed to localize the mass for a biopsy. When that count was off, in that the guide wire could not be located the procedure outlined in policy 7420.03.01 (SPONGE, SHARPS, AND INSTRUMENT COUNTS) was followed. The Policy states: ***A. Discrepancy in Sponge, Sharps and Instrument Counts*** 1. When a discrepancy is reported, the surgeon is immediately notified and a thorough search is made for the item(s). The search shall include: a. Operative site – surgeon and assistant. b. Operative field – surgeon and scrub person.	11/30/09

Event ID: Z69911 4/28/2010 8:05:22AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Kendall R. Fults TITLE: SR. V.P. Clinic Ops (X6) DATE: June 7, 2010

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	Continued From page 1 General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Abbreviations: Dr. - Doctor cm- centimeter FBO- foreign body object IR- Intervention Radiology mm-millimeter OR- operating room Pt 1- Patient one RN- Registered Nurse Based on patient and staff interview, administrative document and clinical record review, the facility failed to implement their policies and procedures for surgical counts titled Counts-Sponge, Needle and Instrument when the guide wire (a wire placed to guide the surgeon to the correct location for surgical intervention) placed in Patient 1 was not accounted for in the OR. This failure led to retention of the guide wire with subsequent pain and suffering from 12/23/08 to 10/6/09. A second surgical procedure was performed on 10/6/09 that was unsuccessful in removing the retained guide		c. Sterile field – scrub person (for vaginal deliveries, the RN and assistant will carefully search the top of and underneath the sterile table, under drapes and blankets, and under the patient's bed as well as infant isolette). d. Operating room – circulating nurse. 2. When the discrepancy cannot be reconciled, an occurrence report is completed by the person who discovered the discrepancy and an x-ray of the operative site pursuant to a physician order is taken before the patient leaves the OR (or delivery room) or procedural area. The policy has also been modified to address the need for an additional count when the patient is moved between departments: "Any time the patient is moved from one department to another the count is taken by the recieving department with the sending department (ie. When guide wire is placed in Radiology and the patient is then transferred to surgery for a biopsy.)	

Event ID: Z69911 4/26/2010 8:05:22AM

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	Continued From page 2 wire and the patient continued to have pain and suffering. Findings: On 10/26/09 the clinical record for Pt 1 was reviewed. The Perioperative Nurses Record dated 12/23/08 documented Pt 1 underwent surgery for removal of a right breast mass on 12/23/08 by. needle localization (wire placed through the breast guided by ultrasound). The Perioperative Nurses Record documented Pt 1 was placed in Operating Room 2 at 1:03 p.m on 12/23/08. The Radiologist and ultrasound technologist were in the room to perform a second needle localization at 1:20 p.m. On 10/26/09 review of the x-ray report dated 9/16/2009 stated "... there are retained foreign bodies present within the soft tissues of the patient about the right shoulder...1-2 mm in greatest dimension...three separate distinct unconnected foreign bodies...the largest 13-15cm in length in the axillary region.... the second is cephalad (towards the head) to the proximal (towards the middle of the body) portion is 1.1 cm in length...Finally there is a 4.1 cm length present in the right anterolateral chest wall, outside the thorax ... The configuration is suspicious for the type of wire utilized to localize lesions in the breast although the hook segment is not clearly identified here." The report indicated the primary care physician was notified. On 10/27/09 at 8:50 a.m. during an interview, Pt 1 stated she went from the Same Day Surgery to Intervention Radiology on 12/23/08 and "about		When a search did not reveal the guide wire, an X-ray was taken per the policy. The radiologist reported the result as negative for a foreign body. While a subsequent review of the film (the week of October 14th, 20100) revealed that the reading was in error, the hospital has a policy approved by the Medical Staff and Governing Board, followed the policy and the policy does address all of the issues needed. The radiology group who employed the radiologist who misread the film of December 23, 2008 has been replaced by a new radiology group. Staff in the surgery department and the other departments which might need to perform extra counts have been in-serviced regarding these policy changes; the training will be completed June 10, 2010.	

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	Continued From page 3 fifteen minutes later went to the operating room." On 10/27/09 at 8:55 a.m. during an interview, Pt 1 stated she began to have pain in her right breast directly after surgery on 12/23/08. Pt 1 described her pain as a "stabbing pain" with shortness of breath when lying down. At her post-operative appointment approximately 1 week later, Pt 1 complained of the pain to Dr.1 and was told it was normal. She stated she was seen several times by Dr. 2 from January 2009 through September 2009 for the pain and swelling of her right breast. Pt 1 stated that later the doctor sent her to physical therapy (massage treatment) because of a "fist sized" bruise. Pt 1 stated she went three times for the massage therapy, but the pain increased and the bruise enlarged. On the third visit the therapist stated the area "felt funny" and sent Pt 1 to outside provider for testing. On 10/27/09 at 9:00 a.m. during an interview Pt 1 stated she was told they were unable to remove the last two wires from her right axilla and right chest wall. Pt 1 stated "I still have pain when I lie down. I am very frightened of the two wires left in me; what if they move? I only went in for a biopsy and now look at me... I regret ever having the surgery, look at how much pain I am in ... Now I can't even sleep I am so scared of these pieces." On 10/28/09 review of the policy titled Counts - Sponge, Needle and Instrument revised 2/18/08 stated "Affected Departments/Services 1. Operating Room, Same Day Surgery, Obstetrics, Cardiac Cath Lab, Radiology, Endoscopy"... and under		Monitor: The hospital will continue to monitor instances of discrepancies in sponge, sharps and instrument counts. Any identified, unresolved, instances will be reported to the surgery committee. Responsible party: Director of Surgery	

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	Continued From page 4 "General Considerations 1. Sharps and other countable items referred to as needles, blades ... must be counted on all surgical procedures" and under "B. Sponge, needle, sharps count: 1. Sharps and sponge counts are performed at the following times: a. Initial - before the procedure to establish a baseline ... e. Additional counts: 3) When a multiple stage operation is performed; 4) when either the scrub nurse or the circulating nurse is relieved permanently, count is taken by the relieving person." (The counting of sharps is to be done in each area, for example: Radiology and Operating Room. When a surgery is done in more than one area the counts need to be done in each area and again whenever there is a change in staff accountable for the patient.) No documented evidence was provided that indicated counts were completed in IR, Same Day Surgery and upon admission to the OR. The intraoperative report dated 12/23/08 did not list the guide wire as part of the count. On 10/28/09 review of the perioperative report dated 10/6/09 indicated Pt 1 underwent a second surgery to remove the retained FBO by Dr. 1. The report indicated the retained FBO was in three places: in her right shoulder, right axilla, and right chest wall. The perioperative record indicated that only the wire in the right shoulder was removed. On 11/10/09 at 8:30 a.m. during an interview, the OR Nurse Manager stated that Pt. 1 was taken from the waiting room of Same Day Surgery to IR on 12/23/08. She stated that in IR a guide wire			

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	Continued From page 6 was inserted into the right breast by ultrasound guided imagery. Pt. 1 was then returned to Same Day Surgery waiting room to await surgery. At 1:03 p.m. Pt. 1 was transferred to the OR for surgery. On 11/10/09 at 8:05 a.m. during an interview, the Risk Management Nurse stated the initial radiologist decided to review the X-ray from 12/23/08, and subsequently changed his findings. On 11/10/09 review of the "In error report" dated 11/9/09 for the initial X-ray of 12/23/08 stated "...corrected report, History foreign body...radiopaque foreign body (localizing wire) in the soft tissue of the right axilla." On 11/10/09 at 10:00 a.m. during an interview, RN 2 stated concerning the surgery on 10/6/09 " they just couldn't get them out...Dr. 1 and Radiologist 2 were unable to retrieve the wire pieces in the right axilla and right chest wall." On 11/10/09 at 11 a.m. during an interview, RN 1 stated it was normal procedure for a patient having needle localization for the patient to arrive in the operating room with a gauze dressing and tape at the operative site. When the dressing was removed, a thin wire would be revealed, extending beyond the skin, with tape around the end and secured beneath the dressing. The dressing would be removed and the area prepared for surgery. RN stated that there was no count completed to account for the guide wire when Pt 1 was brought into the OR. RN 1 stated that on 12/23/08 she			

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	Continued From page 6 removed the gauze dressing from Pt 1 and discovered that no guide wire protruded from the site. RN 1 searched for the wire around the bed and in the bed linens on Pt 1 and was unable to locate the wire. Dr. 1 was notified and a chest x-ray was ordered to check for a retained wire. The Chest x-ray was read as negative. RN1 stated that no further search of the OR or the other areas Pt 1 had been was done. RN 1 stated she "does not count wires placed in other parts of the hospital as part of the surgical count." When asked how OR reconciled the count at the end of the procedure when the wire was removed from the patient she did not have an answer. A second guide wire was placed in the OR. The procedure was completed and the second guide wire was removed. Pt 1 was discharged to home on 12/23/08. On 12/1/09 at 1:50 p.m. during an interview, the Radiology Tech stated that it was not customary to count needles and guide wires used in IR for guide wire placement. The failure to count and account for the guide wire used during the first surgery on Patient 1 and the result of leaving the foreign body in Patient 1, are both violations of the facility's own policies and procedures and the licensee's noncompliance with one or more requirements of licensure, and has caused, or is likely to cause, serious injury or death to the patient. The above facility failures may result in an Administrative Penalty.			

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