CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050701	A. BUILDING _____ B. WING _____	07/17/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Southwest Healthcare System	25500 Medical Center Dr, Murrieta, CA 92562-5965 RIVERSIDE COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit. Complaint Intake Number: CA00298458 - Substantiated Representing the Department of Public Health: Surveyor ID # 25937, 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. Health and Safety Code Section 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. Health and Safety Code Section 1279.1 (c) - "The facility shall inform the patient or the party responsible for the patient of the adverse event by		Initial Comments Southwest Healthcare System received this Statement of Deficiency on May 13, 2014. The hospital reaffirms its commitment to ensure that the surgical count process is followed in order to prevent an unintentionally retained surgical item.	

Event ID: EKED11 5/8/2014 3:11:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE CEO (X6) DATE 5/21/2014

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 7

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	the time the report is made." The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.		Continued From page 1	
	Title 22, California Code of Regulations, section 70223 (b)(2), Surgical Service 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 Based on interview and record review, the facility failed to ensure the "Surgical Count" policy and procedure was implemented for one Patient (Patient 1). A four inch by four inch piece of gauze was left in the patient (Patient 1) after surgical placement of a pacemaker (surgical incision/pocket made into the chest area in which a pacemaker is implanted). As a result, Patient 1 had an additional hospital stay, with two additional surgeries, due to the retained gauze and subsequent infection.		Title 22 California Code of Regulations, Section 70223(b)(2), Surgical Services General Requirements Actions Taken: 1. The Surgical Services Director (SSD) reviewed the incident with the nurse and scrub tech involved in this case and conducted a remedial review of the surgical count process. A performance management action plan was completed which included 100% score on the surgical count quiz and direct observation of the staff members appropriately implementing the surgical count process. 2. The hospital conducted a root cause analysis regarding this case to identify issues that contributed to the retained gauze when Patient 1 underwent a pacemaker insertion. The meeting included OR staff members and leadership, the Chief Medical Officer,	2/3/2012 2/17/2012 2/3/2012

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	Findings: On March 1, 2012, the record for Patient 1 was reviewed. Patient 1, a 79 year old male, was admitted to the hospital on [redacted] 2011, with a diagnosis of atrial fibrillation (an irregular heartbeat). On [redacted] Patient 1 underwent a surgical insertion of a permanent pacemaker. The report revealed two procedure counts, an initial count and a final count, were performed. The final count indicated the sponge count was correct. Patient 1 was discharged home on [redacted] 2012. On [redacted] 2012, Patient 1 returned to the Emergency Department (ED), with complaints the pacemaker site on the left upper chest wall was swollen and painful to the touch. Patient 1 was re-admitted to the hospital with a diagnosis of chest wall hematoma (collection of blood or a clot that has accumulated outside of a blood vessel) vs abscess (collection of pus within tissue in response an infection). An operative report for Patient 1, dated [redacted] 2012, revealed that there was abundant purulent (pus) material in the pacemaker site, and upon further exploration the findings of a 4 inch by 4 inch gauze behind the pacemaker generator (which was extracted). The Operative Report indicated the following procedures were performed: 1. "Dual-chamber pacemaker lead extraction;" 2. "Pacemaker removal."		Continued From page 2 and a risk/patient safety representative. 3. The DSS conducted a case review regarding this event at the February staff meeting. The nurse involved in the case provided his accounting, giving a front-line staff member's perspective. The discussion included a review of the Surgical Count policy, the need for the surgical team to clearly communicate the use of sponges, and awareness amongst the team members including the physician of when the surgical count is being performed. 4. The DSS ensured that the OR staff members successfully completed the surgical count policy quiz. 5. The Surgical Services Director (SSD) coordinated the review and revision of the Surgical Count policy and procedure to clarify the sponge counting process based upon the Association of periOperative Registered Nurses' guidelines. The revisions included the need for the surgeon or assistant to communicate item(s) placed in the wound; for the team to alert the physician that the count process has started; if the sponge package is banded, the band is broken and each sponge is counted	2/3/2012 2/7/2012 2/28/2012

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	3. "Pacemaker pocket debridement" (removal of infected tissue); and 4. "Tissue sampling for culture and sensitivities." Patient 1 remained in the hospital, and on [redacted] 2012, Patient 1 underwent another surgical procedure for reinsertion of the pacemaker implant on the right side of his chest. For 4 days, Patient 1 did not have the pacemaker in place. On March 1, 2012, at 11:50 a.m., the Director of Risk Management (DRM) was interviewed. The DRM stated, the facility did a Root Cause Analysis of the incident. The DRM stated that, according to the operative report, there was only two sponge counts performed (which included the 4x4 inch gauze), and the final count was correct. The DRM could not explain how the count could be accurate when a piece of gauze was left in the patient, or how the gauze was left unaccounted for. The DRM stated she suspected that the surgeon may have placed the 4 inch by 4 inch gauze inside the pacemaker pocket during the final sponge count without awareness by the surgical technician or circulating nurse. On May 29, 2012, at 10 a.m., Registered Nurse (RN) 1 was interviewed. RN 1 stated he was the circulating nurse for Patient 1 on [redacted] 2012. RN 1 stated they did two sponge counts, a preliminary count (done before the surgery begins) and a final count (done at the end of surgery, when the surgeon starts to close the incision). RN 2 stated he started the final count at the beginning of skin closure, and when the count was completed		Continued From page 3 individually, if the wound closure count finishes after the skin is closed, a skin closure count is still required; and the use of a pocketed bag or other system for separating used sponges to facilitate the counting process. 6. The SSD implemented the consistent use of white boars in the operating rooms to track items in and out of the surgical field, including surgical wounds such as a pacemaker pocket; a standardized sponge counter device was implemented. 7. The DSS educated the OR staff regarding sponge counts. The topic of implementing a correct surgical count process was reviewed in unit-based huddles for three weeks, beginning on February 6, 2012. Information highlighted included the need to complete three sponge counts. 8. The SSD collaborated with the Medical Staff Office to ensure each privileged/credentialed surgeon on staff received notification regarding the revision to the Surgical Count policy. This was accomplished via the provider's preferred method of communication, i.e. mail, fax, or email. The notice included the responsibilities	2/28/2012 3/9/2012 3/26/2012

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	the surgeon had already completely closed the incision, so no other count was done. RN 2 was not sure what the policy was at that time, but said it was common practice and acceptable to only perform two sponge counts for that type of small procedure. RN 1 stated he has since learned that there should always (no matter how small the incision) be a minimum of three sponge counts: - Preliminary - prior to the start of surgery, - End of surgery - prior to start of skin closure, and - Final - when incision was completely closed On May 29, 2012, at 10:15 a.m., the Surgical Tech (ST 1) was interviewed. ST 1 stated she was the scrub tech for Patient 1 on [redacted] 2012. She stated it was a routine, quick procedure, for a pacemaker placement. ST 1 stated they did two sponge counts, one prior to surgery, and the second at the first stitch of skin closure. She stated when they were done with the count, the surgeon had already completed the skin closure, and no other count was done. ST 1 stated the policy did instruct them to do a minimum of three counts, but it was common practice to do two counts for that type of procedure. ST 1 stated that is no longer the practice, and all surgical procedures, no matter how small,require a minimum of three counts. On May 29, 2012, at 11:15 a.m., the Surgical Services Director (SSD) was interviewed. The SSD stated the facility policy for Surgical Counts has always been to do a minimum of three sponge counts (the initial, the start of skin closure, and the final). She stated it should never be common		Continued From page 4 of the physician and staff regarding the surgical count process in order to maintain awareness of all sponges, sharps, and instruments used during the course of a procedure. 9. The OR staff participated in the annual competency event. This included a surgical count "station" in which the employees demonstrated competency with the count process technique via direct observation by a member of the OR leadership team. 10. The DSS recommended a further enhancement to the Surgical Count policy to highlight the need for an audible count. The final revisions to the policy were routed to the Department of Surgery, the Medical Executive Committee and the Board of Governors for approval. 11. Circulating nurses and SSTs are educated to the Surgical Count policy and procedure upon hire and annually. Evidence of this maintained in the employee's competency file. (The 2014 annual competency review for surgical staff was scheduled for mid-April to mid-May to ensure that all staff members complete the required elements, including the surgical count process.)	4/26/2012 5/24/2012 Upon Hire and Annually

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	practice to only do two counts for smaller procedures. The SSD stated the case that involved Patient 1 was investigated and it was determined the staff did not do a minimum of three sponge counts as outlined in the policy. In addition, the SSD stated, the surgical staff did not use a sponge counter bag that may have helped to visualize if the count was incorrect. The facility policy entitled, "Surgical Count," dated November 2010, was reviewed. The policy indicates, "The circulating registered nurse will ensure that all surgical counts are performed to account for all items and to lessen the potential for injury to patients as a result of a retained foreign body." The policy also indicates "Sponges are to be counted on all procedures in which the possibility exists that a sponge could be retained. Sponge count will be performed: Before the procedure to establish a baseline... Before wound closure begins. At skin closure or end of procedure... Sponges shall be contained in sponge counter bags. Use of a pocketed bag or other system for separating used sponges may facilitate visualization for counting." The facility failed to ensure their policy and procedure for surgical count was followed, which resulted in a four inch by four inch piece of gauze being left in Patient 1. This failure lead to an infection, an additional two surgeries for removal of the four by four inch gauze and removal and reinsertion of Patient 1's pacemaker, and an additional stay in the hospital for Patient 1. The facility's failure is a deficiency which has caused, or		Continued From page 5 Monitoring: The DSS (or qualified designee) conducts direct observations of the use of a sponge counting device and the count process to ensure staff implement and comply with the Surgical Count policy. The outcome is reported to the Hospital Performance Improvement Committee for analysis and action planning as warranted. The report forwards through the quality oversight structure to the Board of Governors. Person Responsible Chief Nursing Officer	2/28/2012

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	is likely to cause, serious injury or death to the patient This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c)			