CALIFORNIA HEALTH AND HUMAN SERVICE ENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050152	A. BUILDING _____ B. WING _____	01/24/2011

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SAINT FRANCIS MEMORIAL HOSPITAL	900 Hyde St, San Francisco, Ca 94109-4806 SAN FRANCISCO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00254601 - Substantiated Representing the Department of Public Health: Surveyor ID # 23107, 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. T22 DIV CH1 ART3-70223(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. This regulation was not met as evidenced by:		**T22 DIV CH1 ART3-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS** **Immediate Corrective Action:** The hospital policy, "Prevention of Retained Surgical Items" (see attachment labeled 'Appendix 14') was reviewed and revised to include procedures addressing the following: • Separating and sorting sponges after removal from the kick bucket prior to placing in the sponge holder. • Requirement for annual competency review All staff were provided one-on-one training regarding the Sponge Accounting process and the requirement to separate and sort all sponges. The Surgical Services Staffing Guidelines were revised to include language addressing the assignment of non-employee personnel (see attachment labeled 'Appendix 15'). Employees responsible for making staffing assignments were provided education via one-on-one **(Continue to page 2)**	02/03/11 01/20/10 02/03/11 01/12/11

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(JILL WELTON) SENIOR DIRECTOR QA PI 04/19/2012

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.

4/25/12

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	Continued From page 1 Based on interview and record review, the facility failed to develop and implement a surgical count policy and procedure that specified that the circulating nurse separate out each sponge to determine the size, type and number of sponges present after removing it from the kick bucket and before placing in the sponge holder, failed to include the count process in the operating room staff annual competency, failed to conduct audits to ensure compliance with the count process and failed to develop a policy that addressed the issue of two non-employee personnel working together on a complicated case. This resulted in a surgical sponge being left in Patient 1 who had to undergo a second surgery to remove the retained surgical item. Findings: Patient 1 was admitted to the hospital on [redacted]10 for lumbar three (L3) to lumbar four (L4) extreme lateral inter-body fusion and lumbar three to lumbar five laminectomy and fusion with screws. (This was a two part procedure in which the patient was placed in two different positions. The patient was first placed in the right lateral position for an extreme lateral disk approach, complete L3-4 diskectomy and an interior decompression of the spine at L3-4, partial vertebrectomy/diskectomy and L3-4 fusion with cage using nerve monitoring and NuVasive Retractor system. Patient 1 was then placed in the prone position on a Jackson table for placement of posterior pedicle screws at L3 and L5, laminectomy at L3-4 and L4-5, and posterior fusion with local and allograft bone from		**T22 DIV CH1 ART3-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS** conversation regarding staffing guideline revisions. The revisions to the policy, "Prevention of Surgical Items," and the Surgical Services Staffing Guidelines were approved by the Surgical Care Evaluation Committee (SCEC), Medical Executive Committee (MEC) and Board of Trustees, respectively. **Systemic Changes to Prevent Recurrence:** All policy revisions are based on the 2010 guidelines established by the Association of Perioperative Registered Nurses (AORN) and Dr. Verna Gibbs, "No Thing Left Behind." Annual competencies include Sponge Accounting. Validation of competencies is assessed by the successful completion of a written exam and return demonstration (see attachment labeled 'Appendix 7'). Review of staff assignment records **(Continue to page 3)**	01/12/11 01/20/11 02/03/11

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	Continued From page 2 L3-L5). During Patient 1's routine post-op follow up on [redacted]11, lumbar spine x-rays showed a possible retained surgical sponge. Patient 1 was readmitted to the facility on [redacted]11 and had surgery to remove a retained surgical sponge. On 2/22/11, Patient 1's intraoperative record dated [redacted]10 was reviewed and showed that the initial, first and final sponge counts were documented as correct. There was an intraoperative report dated [redacted]11 which listed the surgical procedure as "Spinal Wound Exploration". Patient 1's operative note dated [redacted]11 indicated a pre and post operative diagnosis of retained sponge after L3 (lumbar) to L5 fusion. The description of the procedure included the following" "(Name of Patient 1) was brought to the operating room after informed consent. He was put in the prone position, prepped and draped in the usual sterile fashion. I made a 2-inch laminectomy incision at the prior scar centered over the sponge. I dissected down to the sponge,...Sponge was removed partially adherent to surrounding structures and dissected with blunt and finger dissection. ... Fluoroscopy used to confirm it was completely removed. It was overlying the dura on the inferior aspect of the laminectomy." During an interview on 2/22/11 at 10:10 AM, the Director of Perioperative Services (DPS) stated the circulating nurse and scrub technician involved in Patient 1's surgery no longer work at the facility. She said the staff were "travelers" and their contracts had expired. She said at the time of Patient 1's surgery, the circulating nurse had		**T22 DIV CH1 ART3-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS** are conducted on a daily basis by the Director of Perioperative Services/designee to ensure that at least one member of the nursing surgical team is a hospital employee. All exceptions are approved by the Director of Perioperative Services prior to the start of a case. Approval confirmation is documented by the Director of Perioperative Services on the staffing assignment record. **Monitoring:** 10 random observations per week were conducted to ensure staff compliance Sponge Accounting in accordance with the hospital policy "Prevention of Retained Surgical Items." Audits were performed until (six) 6 months of compliance was maintained at 100%, then quarterly to include a minimum of 40 cases. Aggregate data is a standing monthly agenda item to the Quality Assessment and Improvement (QA&I) Committee, Medical Executive Committee (MEC), and at least quarterly to the Board of Trustees. **(Continue to page 4)**	

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	Continued From page 3 worked at the facility for 10 months and the surgical technician for three weeks. When asked if she thought having two non-employee personnel working together on a complicated surgery had contributed to the sponge being left in Patient 1, she responded "I don't think it contributed, everyone did what they were supposed to." She stated the facility conducted an RCA (root cause analysis) to determine the cause of the retained sponge but "We didn't come up with a definitive answer." The Director of Perioperative Services (DPS) was asked if the RCA explained how the staff followed the facility's policy on sponge counts and a sponge was still left in Patient 1. She said then RCA didn't come up with an answer but one explanation was there was an extra sponge in the room that was put in the sponge holder so the count was correct. She said the extra sponge may have been left in the operating room from a previous case or that "another person" came into the room during the case and left a sponge there. When asked if there was a flaw in the facility's policy that allowed a sponge to be left in Patient 1, she responded "It's an excellent policy, we've taken it one step further to make sure everything is in the sponge holders." The DPS was unable to explain how a surgical sponge was left in Patient 1 during his surgery. The DPS said the facility used sponge holders to ensure that all sponges are accounted for at the end of a case. She said the circulating nurse removes sponges from the kick bucket throughout the case, stretches them out to verify the type and size of the sponge, rolls them up and places them		**T22 DIV CH1 ART3-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS** **Responsible Role:** Director of Perioperative Services CA DEPT OF PUBLIC HEALTH APR 20 2012 L&C DIVISION SAN FRANCISCO	

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	Continued From page 4 in the sponge holders with the blue radiopaque tag visible. She stated it was important that surgical sponges were placed in the holders with the blue radiographic tag visible as this prevented dressing sponges being counted as surgical sponges. She said at he "closing count" which occurs before wound closure, the circulating nurse and operating room technician count all the sponges. she stated the "Final count" occurs after the incision is closed and all sponges are off the surgical field and in the sponge holders. At that point, two people (usually the circulating nurse and the surgeon) verify that the number of sponges in the sponge holders is the same as written on the white board. A review of the facility's Count, Sponges, Needles and Instruments six page policy and procedure (revised 6/12/09) indicated the following: Purpose: Counts are performed to account for all items and to lessen the potential for injury to the patient as a result of a retained foreign body. Procedure: 4. Use of plastic hanging sponge-holders and a dry erase board: This process involves the use of plastic hanging blue-backed sponge-holders which each contain 5 pouches. Each pouch has a thin center-divider which separates each pouch into 2 pockets. One sponge should be placed in each pocket. One sponge per pocket, 2 pockets per pouch and 5 pouches holder means that each holder can			

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	Continued From page 5 accommodate 10 sponges. Each holder will always be set up to hold 10 sponges regardless of type of sponge. Different types of sponges cannot be mixed within one holder. A wall-mounted dry erase board will be used to record operative information including counts. The process will be standardized for use throughout all operating rooms to provide consistency in all types of operative cases. The policy did not specify that the circulating nurse was responsible for removing the sponges from the kick bucket throughout the case or that each sponge was to be stretched out to it's full length to verify the type and size of the sponge, rolled up and placed in the holder with the blue radiographic tag visible to ensure that only surgical sponges were placed in the sponge holders. This had the potential to increase the risk of an incorrect sponge count as a dressing could be placed in the sponge holder which would result in a correct count even though a sponge remained in the patient. The policy did not include any information regarding competency validation. The policy did not specify if the count process was part of the operating room staff annual competency or if observational audits of staff were done to ensure compliance with the count policy. The policy did not show how new staff or non-employee personnel (travelers) would be oriented to the facility count policy. the facility had no process in place to determine the competency of the operating room staff in count procedures. During a follow up interview on 2/22/11 at 2:05 PM,			

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	Continued From page 6 the DPS was asked to explain the difference between what she said was the facility's policy on counting sponges and what the actual policy showed. She said that the facility's count policy was "revised" in January 2011 after the RCA regarding Patient 1. She showed the surveyor a 28 page document (Version 5 December 2010) which had a subject of "Prevention of retained Surgical Items Policy". She said this was a corporate administrative policy and procedure. When asked if this policy had been approved by the facility's governing body, she responded "It has not been approved but it is our policy." She stated a new count process which included the use of sponge holders was "rolled out" in 2009 shortly after she started working at the facility. She said she took information from the corporate policy regarding the use of the sponge holders and "tailored it to fit our facility." She acknowledged that the policy in effect when the surgical sponge was left in Patient 1 did not specify that circulating nurse was responsible for removing the sponges from the kick bucket throughout the case or that each sponge was to be stretched out to it's full length to verify the type and size of the sponge, rolled up and placed in the holder with the blue radiographic tag visible to ensure that only surgical sponges were placed in the sponge holders. In the morning of 2/23/11, the DPS was interviewed regarding staff training on the new count process that was implemented in 2009. She stated all staff received training in the new process and audits were conducted "for a while" to ensure compliance.			

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	Continued From page 7 When asked if the count process was part of the operating room staff annual competency, she replied "I'll have have to look to see if it's included in the annual competency, I don't think we did." she also stated there were no audits done in 2010 to ensure staff compliance with the count process. During an interview in the operating room on 2/23/11 at 10:10 AM, Circulating RN 1 was asked to explain how he would place used surgical sponges in the sponge holder. He said he would remove the sponges from the kick bucket, start at the bottom of the holder, go from left to right and place the sponges in the holder with the blue tag "out." Circulating RN 1 did not say that he would open up each sponge to it's full length to verify the size and type of sponge prior to placing it in the holder. The Association of periOperative Registered Nurses, or AORN, is an organization with input and liaisons including CDC (Centers for Disease Control), Association for Professionals in Infection Control and Epidemiology, American College of Surgeon, American Society of Anesthesiologists and the American Association of Ambulatory Surgery Center. The AORN position papers, standard and recommended practices are widely used not only in the perioperative clinical setting but as an authoritative guide to clarify regulatory requirements. According to 2011 AORN Perioperative Standards and Recommended Practice, pg. 207, "Retained objects are considered a preventable occurrence,			

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	Continued From page 8 and careful counting and documentation can significantly reduce, if not eliminate, these incidents." Recommended Practices for Sponge, Sharp, and Instrument Counts. Recommendation I (pg. 207 & 208). Sponges should be counted on all procedures in which the possibility exists that a sponge could be retained. 3. Accurately accounting for sponges throughout a surgical procedure should be a priority of the surgical team to minimize the risks of a retained sponge. 8. Sponge counts should be conducted in the same sequence each time as defined by the facility. The counting sequence should be in a logical progression (e.g. from large to small or from proximal to distal). A standardized count procedure, following the same sequence, assists in achieving accuracy, efficiency, and continuity among perioperative team members. Studies in human error have shown that all errors involve some kind of deviation from routine practice. Recommendation VI (pg. 213 & 214). Policies and procedures for sponge, sharp, and instrument counts should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting. 1. These policies and procedures should include, but not limited to, items to be counted, directions for performing counts (e.g. sequence, item			

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	Continued From page 9 grouping,...competency validation. Policies and procedures establish authority, responsibility, and accountability and serve as operational guidelines. Policies and procedures also assist in the development of patient safety, quality assessment, and quality improvement activities. Nurses should collaborate with all members of the healthcare team to develop policies that address surgical counts. 3. Practices, policies and procedures are subject to change with advent of new technologies. 4. An introduction and review of policies and procedures should be included in orientation and ongoing education of perioperative personnel to assist them in obtaining knowledge and developing skills and attitudes that affect patient outcomes. On 2/23/11 at 11:50 AM, the surveyors called the AORN to verify the facility's process for removing used surgical sponges from the kick bucket and placing them in the sponge holders. The Perioperative Nursing /specialist stated he would discuss the issue with his colleagues and respond to the surveyors via 1-mail. On 22511, the surveyor received the following response from the AORN Perioperative Nursing Specialist: "You described a situation in which the circulator took the sponges from the kick bucket and placed them in the count bag. The consensus of our group is that in the situation described the circulator should open the sponges to confirm the type, size, and number of sponges present. there could be a			

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	Continued From page 10 situation in which more than one sponge is present and there may be various sizes of sponges stuck and hidden with the typical ball of sponge material present." The facility's count policy did not meet the AORN's acceptable standard of practice when it failed to require the circulating nurse to open each sponge to confirm the type, size and number of sponges present after removing them from the kick bucket and before placing them in the sponge holder. On 2/24/11 at 10:10 AM, the CNO (chief nursing officer) was interviewed and stated the facility had determined that the sponge was left in Patient 1 during the last 15 minutes of his surgery. He said an x-ray taken 15 minutes before the end of the surgery showed no evidence of a sponge. When asked how a sponge was left in Patient 1, he responded "One of the sponge in the sponge holder could have been a 4 x 4 because the sponge retained was a 4 x 8. The CNO stated the facility's policy no longer allowed two travelers to work together in the same operating room unless approved by the director of perioperative services. He said, "It wasn't a deliberate thought to put two travelers in the room during the surgery (Patient 1's) but we were concerned it might have contributed to the retained sponge." He stated that he wasn't sure if the updated policy had been written yet but that "the practice has changed even if the document hasn't changed yet."			

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	Continued From page 11 A review of the facility's undated Surgical Services Staffing Guidelines policy indicated the following: Purpose: To provide appropriate levels of competent nurses and technical staff to deliver competency based perioperative care. Staffing: C. Provision of Staffing Due To Unexpected Increase in Needs Utilization of employees' on-call, per diem, or qualified registry personnel are used when there are additional staffing needs. When possible, non-employee personnel with less than 6 months (name of facility) experience will not be assigned as the primary circulator and primary scrub for the same case. Staffing assignments are made with consideration for patient need and acuity, complexity of procedure, and case mix. According to 2011 AORN Guidance Statement: Perioperative Staffing, pg 609, Perioperative clinical staffing guidelines should be based on individual patient needs, patient acuity, technological demands, staff member competency, skill mix, practice standards, health care regulations, and accreditation requirement.... The perioperative staffing policy should state the minimum number of nursing personnel that will be provided for various types of surgical procedures. Complexity of the procedure may require more than the minimum number of nursing personnel identified.			

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SAINT FRANCIS MEMORIAL HOSPITAL	900 Hyde St, San Francisco, Ca 94109-4806 SAN FRANCISCO COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 12 The facility failed to develop and implement a count and procedure that specified that the circulating nurse separate out each sponge to determine the size, type and number of sponges present after removing it from the kick bucket and before placing it in the sponge holder, to include the count process in the operating room staff annual competency, and to conduct audits to ensure compliance with the count process. The facility also failed to develop a policy and guidelines for operating room staffing that addressed the issue of traveling or registry personnel working together on a complicated case. (In this case, the scrub technician had only worked in the facility operating room for 3 weeks before she was assigned to a complicated spinal procedure with another non-employee circulating nurse). These failures resulted in a surgical sponge being left in Patient 1 who had to undergo a second surgery to remove the retained surgical item, and is a deficiency that has caused serious injury to the patient, and therefore constitutes an immediate jeopardy within the meaning af Health and Safety Code section 1280.1. 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).			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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.