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
	050101	A. BUILDING _____ B. WING _____	10/08/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUTTER SOLANO MEDICAL CENTER	300 HOSPITAL DRIVE, VALLEJO, CA 94589-2594 SOLANO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00203797 - Substantiated Representing the Department of Public Health: Surveyor ID # 21936, 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. Penalty number: 110008357 E 347 T22 DIV5 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.		Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. This Plan of Correction is prepared and/or executed solely because it is required by state and federal requirements for participation in the Medicare and Medi-Cal programs. RECEIVED AUG 26 2011 By _____ E 347 T22 DIV5 CH1 ART3 - 70223(b)(2) Surgical Service General Requirements **Immediate Actions:** At Sutter Solano Medical Center all policies and procedures are approved by the administration and medical staff. This incident was taken very seriously. Upon discovery of incident, we notified the patient and CDPH.	ongoing 09/30/09

Event ID:JELV11 8/4/2011 2:42:36PM

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Angie Hammons, RN BSN	CNE	8/29/11

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.

Notified and accepted on 8/30/11 at 2:39 pm Jessica Contreras, Risk Manager, B. of Dept. HFES

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	Continued From page 1 Based on interviews, record review and policy and procedure review, the hospital failed to ensure Family Birth Center surgical staff implemented the policy and procedure titled, "Cesarean Section - Nursing/OB Tech Responsibilities," regarding sponge counts, resulting in the retention of a surgical lap pad (sponge) in Patient 1's abdominal cavity following a Cesarean Section (surgical delivery of a baby via an incision in the mother's lower abdomen). In addition, the hospital failed to ensure the Family Birth Center's Labor and Delivery (L&D) surgical policies defined specific procedures for performing sponge, needle, and instrument counts and failed to have a system in place to ensure oversight and training of L&D surgical staff. Patient 1 had to undergo another surgical procedure to remove the lap sponge, placing the patient at increased risk for complications due to additional surgery and anesthesia. THIS VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED IMMEDIATE JEOPARDY (IJ) WITHIN THE MEANING OF HEALTH AND SAFETY CODE SECTION 1280.1 THESE FAILURES PLACED THE PATIENT AT RISK FOR INFECTION AND COMPLICATIONS FROM A SECOND SURGICAL PROCEDURE AND ANESTHESIA TO REMOVE THE LAP SPONGE. Findings: During an interview, on 10/8/09 at 9:40 a.m., Administrative Licensed Staff A stated that Patient 1 was brought to the hospital by ambulance on [redacted]/09 in active labor, and the baby was in a breech		**Immediate Actions:** The organization drafted a policy that delineates and outlines the expected methodology for performing sponge, sharps, instruments and/or other countable items on all procedures as well as the roles and responsibilities of the Circulating RN and the Scrub Tech. The policy was approved by the Medical Execute Committee and the Regional Board on 12/09. Policy #OR.F.30 (implemented in Labor and Delivery) utilizes the AORN recommended practices. Emphasis is placed on conducting a visual and audible count simultaneously by the circulator and scrub. Hand off Communication was implemented to address all necessary elements. Documentation: counts are recorded on a standardized pre-formatted, dry erase whiteboard. Intra-Operative documentation of counts is recorded on the Intra Operative Nursing Record. In 2010 the Surgical Count Bar Code system was bought and utilized by the Labor and Delivery Staff. The bar coding system has the potential to meaningfully decrease the risk of a retained sponge in surgery. Current practice requires Labor and Delivery staff to conduct a verbal, auditory, visual, and electronic count. Labor and Delivery Staff were immediately trained and educated: 1. 100% of staff reviewed, acknowledged, and signed the policy. 2. Above policy was approved by Peds/OB and Surgery Department staff and physicians.	10/09/09 11/11/09 12/01/09 10/09/09 10/09/09 10/09/09 12/30/10 10/09/09 11/30/09

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	Continued From page 2 (feet first) position. She stated Patient 1 was immediately transferred to the hospital L&D unit's surgical suite and the baby was delivered via Cesarean Section (C-Section). She stated no complications were noted during the surgery, and the patient and baby were discharged home on [redacted]/09. Administrative Licensed Staff A stated on [redacted]/09, Patient 1 presented to the Emergency Department (ED) with severe abdominal pain. An X-Ray revealed an abdominal mass and the patient was advised to undergo explorative surgery. She stated Patient 1 left against medical advice on [redacted]/09, but agreed to return the next day for surgery. Administrative Licensed Staff A stated the surgery, performed on [redacted]/09, revealed that a surgical lap sponge had been left in the patient's abdomen during the [redacted]/09 C- Section. Administrative Licensed Staff A stated their investigation revealed that the OB surgical technician and circulating nurse did not document that surgical counts were done. During an interview, on 10/8/09 at 9:45 a.m., Administrative Licensed Staff B stated that there was one surgical suite located in the L&D unit. She stated surgical procedures, including procedures for counting surgical lap sponges were covered under a separate Maternal/Child Services policy for C-Sections, and not the hospital's general Surgical Services Departments policies. Administrative Licensed Staff B stated in addition to no documentation that staff performed surgical counts during Patient 1's surgery, they had also identified problems related to surgical procedures, including counts and training of personnel who		3. Eliminated variation by training 100% of the Labor and Delivery Staff through direct observation and annual competency. **Ongoing Monitoring:** Compliance is monitored via random observational audits. Results were 100% 100% audit of the Intra Operative documentation counts recorded on the Nursing record. Results were 100%. **Responsible Parties:** Maternal and Child Health Services Department Manager. **Addendum:** Policy OR.F.30 Counts, Instruments, Sponges, Needles, and Small Items Delineates the following process with regards to the counting process: 11. Sponge, needle, and other counts are performed: a) Prior to incision/start of the procedure (instrument count included) b) Before closure of a cavity, deep or large incision c) When additional countable items are added to the sterile field. d) Before wound/cavity closure begins. (Instrument count included) e) At skin closure or end of procedure Additional counts (sponge, needle, and other) are completed when: a) More than one incision and/or procedure on the same patient. b) Change of scrub nurse (e.g. lunch relief)	ongoing ongoing 10/09/09

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	Continued From page 3 worked in the C-Section surgical suite. She stated the L&D unit had not had an Operating Room (OR) supervisor or manager who provided direct oversight of surgical procedures in the C-Section suite to ensure that L&D surgical staff operated within the same standards as the hospital's Surgical Services Department. During an interview, on 10/8/09 at 10 a.m., Administrative Licensed Staff C stated that the OB Surgical Technician (OB Tech) and circulating nurse were responsible for performing surgical counts. She stated they were to count surgical sponges, needles, instruments together during initial set up and at three different times during the C-Section. The first count occurred prior to closure of the uterus, the second count occurred prior to closure of the peritoneum (the membrane that forms the lining of the abdominal cavity), and the third upon closure of the skin. She stated their investigation revealed only the initial set up count was documented, and there was no further documentation that the other counts were done during or following the surgery. She stated the expectation was that the OB Tech and the circulating nurse performed the counts together and out loud so that the rest of the team could hear. She stated the surgeon and assisting surgeon should pause during each count to allow staff to perform the counts. Administrative Licensed Staff C stated the counts should be documented on a white dry erase board at set up, and then documented on the white board following each count so that the counts were visible to the operating room team at all times. Administrative		c) At time of permanent relief (e.g. change of shift) d) Before any cavity within a cavity is closed (e.g. uterus, bladder, and pericardium). 12. All count sponges and needles will remain within the OR and/or sterile field. a) Linen and trash bags are never removed from OR during the procedure. b) No sponge will go with a specimen c) X-ray detectable sponges will NOT be used for wound dressing 13. The status of sponge and needle counts is kept on the count tally board during the procedure by the RN circulator. Also, things that are used to pack the cavities need to be on the white board. It is the Scrub Tech that is responsible for keeping track of packed items and notifying the circulating nurse. It is the circulating nurse that is responsible for tracking these items on the white board. 14. All counts are documented on the Intra operative Nursing Record as: a) C=correct, W=waived (see #18), NA=not applicable, U=unresolved b) Surgeon will be notified of count c) If count is waived, reason is documented 15. The surgeon must be informed by perioperative personnel (nurse or OR technician) when any discrepancy in a count of surgical items is discovered. It is imperative that an appropriate search be undertaken to recover the item in question and resolve the discrepancy. Concerns of perioperative personnel about a discrepancy must be communicated to the surgeon and never dismissed without appropriate investigation and actions. Efforts should be made to inspect all possible sites in and around the surgical field	

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	Continued From page 4 Licensed Staff C stated she managed the entire Maternal Child Health Department, which included the L&D and the OR suite. She stated prior to the incident, she had not conducted any reviews, observations or evaluations of staff during surgery to ensure surgical procedures were followed. She stated they did not have a manager who provided direct oversight of procedures in the OR suite and stated they had not conducted chart audits for quality review to ensure documentation was completed in accordance with policy. During an interview, on 10/8/09 at 11:15 AM, Licensed Staff D stated that she was the circulating nurse during Patient 1's C-Section as well as the patient's primary nurse. She stated that it was sometimes difficult to perform all of the tasks required to prepare the patient for surgery, as well as conduct the duties of the circulating nurse in the operating room, especially during an emergency. She stated the night of Patient 1's surgery, the charge nurse assisted with preparing the patient for surgery which gave her time to conduct the initial set up pre operative count with OB Tech E. Licensed Staff D stated that lap sponges came in packs of five and had a piece of breakable tape that held the packs in place. Licensed Staff D stated she could not recall specifically how she and OB Tech E conducted the counts during Patient 1's surgery. She stated usually OB Tech E removed the sealant tape, and held up each pack of five lap sponges, and showed Licensed Staff D the edges of the lap sponges and counted out loud to confirm that there were five in the pack. She stated the count continued in that manner, until they obtained		for the missing item. If the item is not located, an over-penetrating X-ray is taken and read by the surgeon, radiology consult will be requested at the surgeons' discretion. 16. In the event of an unresolved count, the OR is searched again once the patient is transferred. All table linens, drapes, trash, etc. are searched for the missing item. If found, the surgeon is notified immediately and the Intraoperative Nursing Record is updated accordingly. 17. Pre-operative and post-operative surgical counts and other requirements described above may only be omitted in an extreme patient emergency. In such cases, the divergence from standard practice must be documented. In these cases, performing an X-ray to rule out a retained surgical item must be accomplished while the patient is in the OR or Post Anesthesia Care Unit (PACU), unless contra indicated by the patient's clinical condition.	

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	Continued From page 5 the usual count of 20 sponges. Licensed Staff D stated she wrote the total amount of sponges on a white dry erase board. Licensed Staff D stated she recalled that she and OB Tech E conducted the three required counts during surgery, but she did not document the counts on the operative report, and she did not have OB Tech E sign the verification of counts, as she should have done per policy. She stated when she and the OB Tech conducted the required counts, the OB tech called out what she had on the field, which included the operating table, on or in the patient, and on the Mayo Stand (a table near the surgeon and OB Tech which contained the sterile instruments and supplies used during surgery). Licensed Staff D stated she counted what was in the sponge pockets (individual pouches where used surgical sponges were collected) or in the discard bucket and they ensured that the total was correct. Licensed Staff D stated that because she was not sterile, it was not possible for her to see the operating field, so she did not visualize the lap sponges or other items that the OB Tech counted and called out. She stated it was a matter of "trust" that the OB Tech informed her of the correct counts of sponges that the OB Tech had visualized, and the OB Tech also trusted what Licensed Staff D had counted. Licensed Staff D stated that after the incident with Patient 1, she realized the problem with the way they did their counts was that at no point, were all of the sponges in her field of vision at one time. She stated that at the end of surgery, she never saw a final sponge count. Licensed Staff D stated she had worked in L&D for four years and attended an offsite class that			

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	Continued From page 6 instructed on operating room procedures when she was hired. She stated she did not recall receiving any recent training regarding operating room and surgical count procedures. During an interview, on 10/8/09 at 11:48 a.m., Physician F stated that she was the surgeon who performed Patient 1's initial C-Section on [redacted]09 and also the surgery on [redacted]/09 when the retained foreign object, the laparotomy (lap) sponge, (also referred to as a sponge or lap tape) was discovered. She stated the retained sponge was a thin piece of gauze like material that measured about 18 inches x 18 inches when opened. Physician F stated that she documented on her dictation note that the three required counts were correct during the [redacted]/09 C-Section. She stated she would not have documented that if she did not hear Licensed Staff D and OB Tech E verbalize that the counts were correct. Physician F stated that Patient 1's retained lap sponge was found in the right pericolic gutter (the space between the colon and abdominal wall). She stated that because she concentrated on performing the surgical procedure, she did not usually pay attention to how the OB Tech and circulating nurse performed the counts; she just listened for them to verify out loud that the counts were correct. She stated that if at any time the counts were not correct, she expected the OB Tech and circulating nurse to inform the team so that the item could be located. She stated due to where the lap sponge was found, it should have been detected after the first count. She stated that it was likely that all three counts were incorrect. Physician F stated that the expectation was that			

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	Continued From page 7 both staff who was responsible for conducting the counts visualized all sponges simultaneously during the counting process. She stated that the circulating nurse was expected to visualize the field while conducting the count. She stated that if the circulating nurse was not able to visualize what was on the field, then the circulating nurse should ask the surgeon or OB Tech to show them the item, whether it was on the field or in the patient's body. She stated that it was the purpose of having two people verify the count and stated she had not been aware that they did not both visualize the lap sponges at the same time. Physician F stated that while the OB Tech and circulating nurse conducted the counts she continued to perform surgery; however she could stop at anytime if staff needed time to conduct a correct count. Physician F stated she did not do routine sweeps to look for sponges, etc., prior to closure unless there was an indication to do so. During an interview, on 10/8/09 at 2:05 p.m., OB Tech E stated that nothing significant stood out regarding Patient 1's surgery, other than it was an emergency procedure. She stated Licensed Staff D arrived and was present in the OR when she did her initial count of supplies, including the lap sponges. OB Tech E stated that because the table that she placed the supplies, including lap sponges, was a sterile field, Licensed Staff D did not stand next to her at the table. OB Tech E stated she could not specifically recall where Licensed Staff D was when she performed the initial counts for Patient 1's surgery, but stated that usually, after she removed the tape from each package of five lap sponges,			

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she called out what she had counted and sometimes she held up the package of sponges to allow Licensed Staff D to see the package. She stated that she could not recall if she did that while they prepared for Patient 1's case. OB Tech E stated that she usually started the sponge count by verbalizing how many lap sponges were on the surgical field and on the Mayo Cart. Then the Circulating Nurse would verbalize how many lap sponges she had in the bucket or in the pockets. OB Tech E stated that sometimes she tried to visualize what the circulating nurse counted, but stated she often could not do that because she had to be prepared to pass instruments or assist the surgeon and she often could not stop to visualize and confirm the count with the circulating nurse. OB Tech E stated that she could not specifically recall when she last had training regarding surgical count procedures, but stated it had been a long time.

Patient 1's record, reviewed on 10/8/09, included a Report of Operation dated [redacted]/09. The pre-operative and post-operative diagnoses included that Patient 1 had an intrauterine pregnancy, with breech presentation in active labor, and the patient received a low transverse cesarean section. Physician F documented that the sponge, laparotomy tape, and needle counts were correct three times, and the patient tolerated the procedure well.

Review of the Pre-Operative Checklist/Intraoperative Nursing Care Plan, dated [redacted]/09, documented that Patient 1 was in the room at 3:25 a.m. and surgery

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	Continued From page 9 began at 3:44 a.m. The section for counts documented the Pre-Op sponge, needle and instrument counts were performed. Licensed Staff D initialed that the pre-counts; there was no documentation that OB Tech E verified the pre-counts. There was no further documentation that the first, second and third counts during surgery were performed. There was no documentation the surgeon was notified of the count, or any indication that the counts were unresolved. Review of the Report of Operation, dated [redacted]/09 for Patient 1, documented the pre-operative diagnosis was right pelvic abscess, suspicious for foreign body versus ruptured appendix. The post-operative diagnosis was a retained foreign body post Cesarean section and the patient underwent an exploratory laparotomy, under general anesthesia, with removal of foreign body (retained laparotomy tape). The findings indicated the laparotomy tape had walled off into the right adnexal area, to the right of the umbilicus in the right pericolic gutter. The surgeon documented that there were no complications noted and the cavity where the sponge was found and the remainder of the abdominal cavity was explored manually. The liver and gallbladder were felt and palpated and no abnormalities were noted. No other retained foreign bodies were noted in the exploration of the abdominal cavity and no other suspicious areas had been seen on the patient's CT scan. Review of the Discharge Summary, dated [redacted]/09, documented that Patient 1 underwent a C-Section on [redacted]/09, and was ultimately discharged home			

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	Continued From page 10 from that hospital visit after having a temperature one day post-operative, and underwent an abdominal ultrasound which was suspicious for gallstones, and was treated with antibiotics. Patient 1 was seen two weeks post-operative from the C-Section at a local clinic and reported that she initially had severe pain post-operatively, but by the time of the two week post-operative visit, was feeling well and the exam at that time was unremarkable. The patient failed further follow up appointments. Review of the Discharge Summary documented that, Patient 1 presented to the ED on [redacted]/09, with a complaint of five days of worsening right lower quadrant pain. A Computed Tomography (CT) scan (a type of X-Ray) was done and was suspicious for retained foreign body with a differential diagnosis of possible ruptured appendix that had walled itself off. The patient presented back to the hospital on [redacted]/09 and underwent exploratory laparotomy, and the findings confirmed that there was a laparotomy tape in the patient's right pericolic gutter. The patient was discharged home two (2) post-operatively in stable condition. Review of the policy and procedure titled "Cesarean Section - Nursing/OB Tech Responsibilities," revised 1/2007, on 10/8/09, indicated responsibilities of the Scrub Nurse/ OB Tech prior to surgery was to set up the "Back" table with all supplies. Responsibilities of the circulating nurse indicated that when the scrub nurse/OB Tech had set up the back table and was ready to count, the circulator nurse counted with the scrub			

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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050101	A. BUILDING _____ B. WING _____	10/08/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUTTER SOLANO MEDICAL CENTER	300 HOSPITAL DRIVE, VALLEJO, CA 94589-2694 SOLANO COUNTY

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	Continued From page 11 nurse/OB Tech and completed the count form and wrote the count for lap tapes and needles and instruments on the dry erase board. The responsibilities of the circulating nurse indicated that three counts were taken during the C-Section: Upon closure of the uterus (sponge and needles only); upon closure of the peritoneum (sponge, needle and instruments), and upon closure of the skin (sponge and needles only). If the count was incorrect or omitted, an abdominal X-Ray was obtained prior to leaving the surgical suite. The circulating nurse obtained the scrub nurse/OB Tech's signature on the Pre-Operative Checklist/ Intra- operative Nursing Care Plan, and completed and signed the sheet. Responsibilities of the scrub nurse/OB Tech during surgery included to perform the pre-surgical count of lap tapes, needles and instruments with the circulating nurse, replaced soiled sponges with dry sponges as necessary, try to be aware of all sponges (and observe if the surgeon used for packing). Count any additional sponges as they were handed onto the field. Count all lap sponges and needles at closure of the uterus, peritoneum and skin and count instruments at closure of peritoneum. Inform the surgeon audibly of outcome of the count. The policy did not direct staff in how to specifically and consistently perform the counts, or the importance that both staff responsible for counting visualized the counted items simultaneously and did not include procedures to ensure that the surgical team allowed time for the counts to be performed (such as a surgical pause).			

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