CA DEPT OF PUBLIC HEALTH

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
	050454	A. BUILDING _____ B. WING _____	06/30/2011

FEB 27 2012
L&C DIVISION
SAN FRANCISCO

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UCSF MEDICAL CENTER	505 Parnassus Ave, San Francisco, Ca 94143-2204 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: CA00273112 - Substantiated Representing the Department of Public Health: Surveyor ID # 26616, 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)(1)(D) Retention of foreign object in a patient (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. T22 DIV5 CH1 ART3 - 70223(b)(2) (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation		The UCSF Medical Center Patient Safety Committee (PSC) conducted a comprehensive, multidisciplinary review of the event that occurred on June 9, 2011, referenced in the findings. Following review of the event, the PSC developed and directed an action plan to be implemented in perioperative service sites (Parnassus/ Moffitt Long OR, Parnassus ASC, Mount Zion OR, Orthopedic Institute, and Labor and Delivery). At the direction of PSC, the Director of Perioperative Services implemented improved education, communication, auditing and monitoring measures to better address consistent application of the surgical sponge count policy and procedure in the department and reported on the status of these activities to PSC on June 22, 2011 and again on July 20, 2011. Additionally, beginning October 4, 2011, the Director of Perioperative Services provided monthly status reports regarding continued	6/15/11 6/22/11 7/20/11 & ongoing 10/4/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Steve Maruzzi TITLE Director, Regulatory Affairs (X6) DATE 2/15/12

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2/21/12

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	Continued From page 1 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. These regulations were not mot as evidenced by: Based on interview and record review, the hospital failed to ensure that its surgical services were delivered using acceptable standards of practice, maintaining compliance with applicable regulations and guidelines governing surgical services, when two operating room nurses failed to perform a sponge count according to the facility's policy. This failure directly resulted in the retention of a laparotomy sponge in the abdominal cavity of Patient 1, who had to undergo a second surgery and anesthetic to remove it. * RN 2 documented the counts as correct on the electronic record before all the sponges had been reconciled with the scanner. * They ignored the request of ORT 1 to reconcile a sponge count discrepancy, a fact he announced "more than once". * They neglected to call for additional assistance from the charge nurse during a disputed sponge count. * RN 2 failed to scan out the laps from the ring stand and place them in the counter bags. Instead, she "visually"counted them directly from the ring stand and delayed scanning them while she counted instruments.		implementation of the action plan and monitoring and auditing activities to Quality Improvement Executive Committee (QIEC) for additional review and oversight, to continue until the QIEC determines an alternative reporting period for such matters. The PSC reports to QIEC. QIEC reports to the Executive Medical Board (EMB) which in turn reports to the Governance Advisory Council (GAC), the designated Governing Body. Regarding RN 1 and RN 2, they were interviewed, delivered a notice of intent to terminate, and terminated for noncompliance with the surgical sponge count policy and procedure. On June 14, 2011, the Obstetrics, Gynecology, and Reproductive Sciences Department's Mortality and Morbidity Committee reviewed and discussed the incident.	6/17/11 7/13/11 8/18/11 8/22/11 6/14/11

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	Continued From page 2 * They failed to maintain the sterility of the field and the room before confirmation that the wound was clear of sponges. They knew a lap sponge was missing, and assumed it "had to be in the trash". * They failed to notify the surgeon that a sponge could not be found. She had no knowledge that the count was in dispute and had no reason to do a manual sweep of the operative site before the skin was closed. * RN 1 failed to call for a STAT x-ray to rule out foreign body retention. Findings: Patient 1 was an 85 year old admitted to the medical center on [redacted]11 with advanced stage high-grade ovarian cancer who underwent an exploratory laparotomy (abdominal operation), tumor debulking (removal e part) including supracervical hysterectomy(removal of uterus), transverse colectomy (excision of colon) and omentectomy on the same day. On [redacted]11, after Patient 1 had been stabilized in the ICU, she was returned to the operating room on [redacted]11 to remove a retained laparotomy sponge, discovered by the surgeon between the edge of her liver and right diaphragm. A 6/28/11 review of the patient's [redacted]11 intraoperative record indicated that the final counts were "correct". In the afternoon of 6/29/11, a series of interviews were conducted at the MZ campus with staff involved in the first case (surgery) on [redacted]11, whon the laparotomy sponge (18" x 18") had been retained.		Beginning June 15, 2011, a formal retraining of perioperative nursing and operating room surgical technologist staff regarding the surgical sponge count competency was implemented in intensive, individual or small group (3-4 staff members) sessions, with each session requiring 60-90 minutes of detailed interactive education. The purpose of such sessions was to permit the evaluator to review and assess each individual's competency with the surgical sponge count policy and procedure, identify any individual deficiencies unique to the staff member, and permit immediate corrective action for each staff member, as needed. The detailed and intensive interactive surgical sponge count competency assessments enabled UCSF Medical Center to implement a process to assess and establish system-wide adherence within the perioperative department staff to the surgical sponge count policy and procedure. By September 1, 2011, all active perioperative department nursing and operating	6/15/11 9/1/11

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	Continued From page 3 At 12:05 p.m. RN 3 said she was working the 11 a.m. to 9 p.m. shift on that day. She brought Patient 1 to the operating room from the pre-op unit. "RN 4 (Charge Nurse) was helping set up the room and doing the (initial counts) until I got into the room (to resume the lunch break for RN 1). I stayed until the permanent people returned. I left at 1:15 p.m. The patient was still not asleep when I left". On 6/29/11 at 12:40 p.m. the [redacted]11 RN 4 told surveyors that he had also worked the 11 a.m. to 9 p.m. shift that day. He said he was helping during a 30 minute lunch break for RN 1, who was the circulating nurse on the case. "The patient was not in the room yet. I got the room set up, did the initial count (instruments, sponges, and needles) with Operating Room Technician 1 (ORT 1). I scanned in all the sponges with ORT 1. When I left, the patient was still not in the room". On the same day at 12:48 p.m. RN 2 was interviewed. She told surveyors she was out in the substerile room gathering supplies for another case when she met RN 1 who looked tired, and asked her if she had time to give her a 15 minute afternoon break. She checked with the charge nurse (RN 4) and went into the room to give RN 1 a break. "They were just about to start the first count; they were closing the peritoneum. We counted the Bookwalter retractor pieces (a large self retaining abdominal retractor which is attached to the OR table by the surgeon and the circulating nurse). Some of the sponges were in the (sponge counter)		room surgical technologist staff received surgical sponge count competency review. For staff on leave of absence and new hires, each staff member receives a surgical sponge count competency training and assessment following return to work or prior to beginning work as a new employee. Formal assessment of surgical sponge count competencies is now included as part of the annual competency review of perioperative department staff. As part of the PSC review and action plan, 6 key reminders were identified to be stressed with perioperative nursing and operating room surgical technologist staff for increased awareness and retention of the surgical sponge count policy and procedure. Collectively, the 6 key elements were referred to as "Pause for the Gauze Reminders" and distributed to perioperative nursing and operating room surgical technologist staff as a handout or lanyard card to be attached to identification badges for purposes of continuing	Ongoing ongoing 6/15/11

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	Continued From page 4 bags and about 5 or 6 were still in the ring stand". RN 2 further stated "I grabbed them in my hand, they were very wet, and counted manually with ORT 2 so he could see them. I'm not sure if he saw what was in the ring stand. I dropped them in the bucket so he could see them. ORT 2 counted what he had on the field and the back table. I didn't scan them at that time. Too much time. They were still closing. I put them back in the bags to scan later. I finished counting the small items, needles, instruments. Very busy case, a lot of changes. At the end of the instrument count, ORT 1 returned from his break and counted a 12 item GYN specialty set. ORT 2 was now leaving. The surgeons were finishing closing. They were putting in the (skin) staples. We counted sponges, needles and the small items (e.g. Bovie tips, knife blades, etc.) The policy says there should only be 2 sponges (one wet and one dry) left at the end of the case for patient cleanup, but that's not the reality. There were at least 10 sponges left on the field". "RN 1 came back from her break. I (RN 2) told her everything was ok as far as the manual count, but we still hadn't scanned the sponges on the field. The surgeons were taking the drapes off. ORT 1 scanned the sponges on the field. He announced, "I'm missing a sponge". "RN 1 and I (RN 2) searched everywhere. It was 'fuzzy' as far as the time Physician 1 left the room to talk to the family. The resident and the fellow were stapling. I was comfortable that we actually had seen all the sponges. The anesthesia attending		education and retention of critical points in the surgical sponge count policy and procedure. By July 22, 2011, all active operating room registered nursing staff confirmed review and receipt of the "Pause for the Gauze Reminders" in writing. For operating room registered nursing staff on leave of absence, each staff member receives the "Pause for the Gauze Reminders" handout or lanyard and confirms review and receipt in writing prior to a scheduled operating room case assignment. As part of the new hire orientation for operating room registered nursing staff, each new hire receives the "Pause for the Gauze Reminders" handout or lanyard and will confirm review and receipt in writing. For operating room surgical technologist staff on leave and new hiree, each staff member will receive the "Pause for the Gauze Reminders" handout or lanyard for purposes of continuing education and retention of the surgical sponge count policy and procedure following return to work	7/22/11 Ongoing Ongoing

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	Continued From page 5 who came in to help the anesthesia provider doing the case asked, 'What do we have to do (regarding the missing sponge)?' I told RN 1 to take care of that. I went through all the bags, and wasn't privy to what went on between them (anesthesia and RN 1). All of a sudden, we're on our way to ICU. The patient wasn't crashing, but she was hemodynamically unstable". RN 2 told surveyors that apparently there were 2 sponges packed behind the liver that she was unaware of. "They took one out. RN 1 wrote it on the white board but didn't tell me about it. An x-ray was done in ICU which was negative, but we continued to look everywhere in the room. We thought the likelihood of a spongo being in there (the patient) was so small". Surveyors asked RN 2 if Physician 1 (surgeon) was the type of surgeon who would be uncooperative with the count process. She answered, "They were all tired. It was a long case, but I think if at any point we had said something to her about the possibility of a missing sponge, she (Physician 1) would have gone back to check". She added, "We have been so good, we got too comfortable. We thought, 'it can't be in there (the patient)". RN 2 said that around 8 p.m., the team searching for the sponge in the empty operating room told Physician 2 that they were unsuccessful in locating it. Physician 2 (surgical fellow)informed them that the x-ray had been negative. Surveyors asked RN 2 when they notified the charge nurse about the missing sponge. She said she wasn't aware of that. She said when RN 4 was finally notified, he called		or prior to beginning work as a new employee. On September 29, 2011, the Director of Perioperative Services distributed additional education via email to perioperative nursing and operating room surgical technologist staff reinforcing the "Pause for the Gauze Reminders" and redistributed lanyard cards to all perioperative sites mentioned above. On June 22, 2011, and June 29, 2011, at Mount Zion OR and Parnassus/Moffitt Long OR, respectively, staff in-service education sessions were conducted that reviewed the surgical sponge count policy and procedure as well as a detailed discussion of the incident. The presentation focused on communication techniques and improvements in the operating room regarding the surgical sponge count policy and procedure, the policy points that were not met during the incident that resulted in a retained lap sponge, and the expectation of mandatory .	1/29/11 6/22/11 6/29/11

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	Continued From page 6 the Periop Manager and put her on the phone to talk to her about it. Finally, surveyors asked why she hadn't called for some help when she found herself having to deal with the multiple counts and scrub personnel changes on a case she hadn't been in on from the start. She answered, "It felt doable. I felt it was under control at the time." She also added that she was the nurse who charted that the counts were correct, because "the manual counts were correct". Following this interview, RN 1 was interviewed at 1:40 p.m. She told surveyors that she took over from RN 3 after she returned from a lunch break at 1:05 p.m. She said RN 4 did the initial count and spoke with the patient. When she arrived back in the room the patient was still on a gurney and RN 3 was helping the anesthesia provider with the epidural. She said she just "jumped in there" and took over. She said it was a very busy start, with having to get positioning aids, extra suction cannisters to handle the patient's ascites (fluid in abdomen), blood tubes sent to the lab for blood transfusions, and getting a headlight on Physician 1, which was unexpected since "she usually doesn't wear one." She also had to open a number of instrument trays, including 2 bariatric Bookwalter retractors (self retaining abdominal retractor which attaches to the OR table, adjusted by the circulating nurse under the sterile drapes), and had numerous specimens to process. She said the patient was "bleeding like heck, anesthesia was giving her FFP (fresh frozen plasma) and I was giving ORT 1 ten laps at a time."		compliance with the surgical sponge count policy and procedure. On June 30, 2011, the incident was reviewed and discussed at the Anesthesia Resident Conference, providing education regarding the role and responsibilities of the anesthesiologist as part of the surgical team in the surgical sponge count policy and procedure. This education included communication on the importance of supporting the nurses in the surgical sponge count process. On July 6, 2011, the incident was reviewed and discussed at the Department of Anesthesia Quality Improvement Conference with anesthesia faculty and residents and included education regarding the need for physicians to support the consistent application of the surgical sponge count policy and procedure. On July 8, 2011, the Medical Director of Perioperative Services presented to the Operating Room Committee	6/30/11 7/6/11 7/8/11

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	Continued From page 7 She (RN 1) said, "I usually initial the sponge bags with my initials and the initials of the scrub, but not this time, I was just too busy. At 5 p.m. RN 2 came in the room. I asked her, 'Are you here for my p.m. break?' She said, 'No, but I will find out.' Then ORT 2 came in to relieve ORT 1. He (ORT 2) was already scrubbed in and ORT 1 had just left when RN 2 came in to relieve me. I came back from my break at about 5:20 p.m. and saw the patient undraped, with the dressing gauze on the abdomen. I helped Physician 2 (surgical fellow) put the Elastoplast on (pressure dressing tape). I saw ORT 1 looking in the trash for a lap sponge. I don't remember if Physician 1 was in the room at the time. I turned to RN 2 and ORT 1 and said, 'Do both of you swear you visualized your laps?' They told me the counts were fine but we're missing a lap, which is probably in the trash. We really didn't believe it was in the patient". Surveyors asked RN 1 whether she told anyone about the packed sponges. She answered, "I did write on the board that there were 2 sponges packed under the liver but I didn't tell RN 2 when she relieved me". When surveyors asked RN 1 how the count could be correct if they hadn't all been scanned, she replied, "Only recently has it become policy that the count is only correct when the manual final count, the written (on the white board) count and the electronic (Surgicount scanner) counts are identical. The scanner was a supplemental counting measure until a few months ago". She continued, "We told Physician 2 and anesthesia (anesthesia care providers) we are supposed to get an x-ray because we are missing a lap sponge, but		a review of the incident, a historical overview and discussion of past issues with retained sponges, the continued need to review and consistently implement the surgical sponge count policy and procedure, and the importance of facilitating and responding to communication regarding additional time for surgical sponge counts and any concerns related to surgical sponge count variances. The OR Committee membership includes surgeons from various surgical services and anesthesiologists from the Department of Anesthesia who share the information with their respective surgery and anesthesiology colleagues. On July 13, 14, and 20, 2011, the Director of Risk Management presented education and training regarding the importance of the role of the nurse in the operating room and expected professional accountability for compliance with operating room policies, including, but not limited to, the surgical sponge count policy and procedure. This	7/13/11 7/14/11 7/20/11

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	Continued From page 8 we highly doubt it's actually in the patient. They (Physician 2 and anesthesia staff) said, 'What do you want us to do?' They were keeping the patient intubated, had to call the ICU for a vent (ventilator). I didn't know who was still looking at this point because I was focused on the patient. I was looking at all the possibilities. The room was already contaminated. The sponge can't be in the patient. Thinking the count was correct, and 99% of the time (a missing sponge) is found in the trash, I went with the patient to ICU. It was close to 6 p.m. when I told Physician 2 they couldn't find the sponge after searching everywhere. I called x-ray told them we had a possible retained surgical sponge. I left at the end of my shift, because I didn't know what else I could do". Physician 2 (surgical fellow) was interviewed next, at 2:55 p.m. on the same afternoon. She told surveyors that the nurses told her that the past two counts were correct. "They didn't specify that the scanner count wasn't done or complete. They said they were looking for a sponge but gave me the impression that they were going to find it in the room". The final interview on 6/29/11 was at 3 p.m., with ORT 2. He told surveyors that around 5 p.m. on [redacted]11, he came in to Patient 1's room to give a scrub break to ORT 1 for 15-20 minutes. He said, "RN 2 came in after me. ORT 1 didn't mention there were sponges under the liver. He and I counted needles and small supplies, what I could see on the (sterile) field. 5 minutes after I came in we started to close. I told RN 2 we need to start		education was recorded and is available for future training, as needed. On August 17, 2011, the Anesthesia Department's Mortality and Morbidity Committee reviewed and discussed the incident. On August 23, 2011, EMB reviewed and approved reports from PSC discussing the incident, issues identified following review of the incident, and risk reduction strategies. On September 27, 2011, EMB reviewed and discussed the incident and had a follow-up discussion at the October 2011 meeting to review details of the status of implemented education, communication, monitoring and auditing measures to address consistent compliance with the surgical sponge count policy and procedure. On September 29, 2011, the Chief Medical Officer distributed education to anesthesiology and surgery faculty and residents highlighting the "Pause for the Gauze Reminders," key elements of the surgical sponge count policy and procedure, the importance of	8/17/11 8/23/11 9/23/11 10/25/11 9/29/11

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	Continued From page 9 counting. We were getting the laps out (of the abdomen), and I threw them in the kick bucket and started the first count, starting with the field, the Mayo stand, and then the back table. RN 2 showed me the sponges, hung on the side of the ring stand. I was able to count (lap) sponges, needles, small things. I didn't count the last instrument set (12 pieces). ORT 1 came back in the room. I assume he counted it with RN 2. I know there were still sponges to count. They (physicians) continued to close. I wasn't there for the final count, but when I left we were not scanning anything in." ORT 1 was interviewed the following morning, 6/30/11 at 2:35 p.m. He told surveyors that he was the main scrub for Patient 1's case. "Around 4:45 p.m. ORT 2 came in and relieved me for an afternoon break. They were still working. The abdomen was open, and self retaining retractors still in place. I wasn't anticipating closing for about another hour. I came back from my break around 5 p.m. and I was surprised because they were starting to close. ORT 2 and RN 2 were doing the first count. By the time I got my gown and gloves on they were just about done with the first count. They notified me everything was accounted for. They said the first count was correct; instruments, sponges, small items. I know that all sponges must be scanned once they are off the field. They were ready to start the skin closure so I requested RN 2 to start the count. The final count does not involve instruments. We started with the laps (18" x 18") or raytex (4 X 8 gauze sponges) on the field, then the Mayo, and the back table. I know I only had 3 sponges left; 1 next to the surgeon, and 1 wet and		facilitating and responding to surgical sponge count concerns, and the need to allow sufficient time for perioperative staff to complete surgical sponge counts in accordance with the policy and procedure. On September 29, 2011, UCSF Medical Center's Governing Body (i.e., GAC) reviewed the initial and recent retained sponge incidents referenced in the findings. Additionally, the Governing Body reviewed and ratified the PSC's actions, the surgical sponge count policy and procedure, the "Pause for the Gauze Reminders" education materials and training, the revised surgical sponge count competency evaluation tool, the revised observational audit tool, and corrective action measures that have been and will continue to be implemented to establish system-wide compliance with the surgical sponge count policy and procedure. At the direction of the Governing Body, the Chief Operating Officer and/or other designated UCSF Medical Center representatives will	9/29/11

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	Continued From page 10 1 dry on the Mayo stand for clean up". ORT 1 continued to state "The ring stand had a plastic cover on it. My nurse (RN 2) had laid the sponges out on the ring stand. She pointed out the laps, but without picking each one up, from my perspective they were hard to see. (Facility policy indicated the scrub and circulator together will manually, audibly and visually count the sponges). The strings were not hanging out. The sponges in the ring stand weren't scanned yet. We verified a correct count, but the sponges weren't scanned. The patient was closed. I helped clean, and gave a cleaning sponge to the resident. I made sure I had my last 3 laps. When I scanned them out, I was missing one. I looked in the trash and announced to the team that I was missing a lap. I did this more than once. The patient was still on the table, intubated. I asked for some help and another ORT came in. I remember that I mentioned we can't leave the room because we need an x-ray. I don't know when the patient left. Later, I was told that the x-ray they took in the ICU was negative. I couldn't accept that. At 7:15 p.m. we were still looking, checking everything and everywhere. I remember the area she (Physician 1) packed the laps in. I didn't mention it to ORT 2 when he came to relieve me, but RN 1 wrote it on the white board. I told RN 4 before I left for the evening, 'Please get another x-ray, I really think it is in the patient'. "When I came back to work on Monday, I heard that they brought the patient back to surgery on Saturday. That lady (Patient 1) was really sick. We could have killed someone.		report on the status of the action plan measures at future Governing Body meetings. Monitoring and Auditing: Beginning June 15, 2011, the volume of cases reviewed as part of the ongoing, random observation audits of compliance with the surgical sponge count policy and procedure was increased to 10% of the total surgical volume for each perioperative site (Parnassus/ Moffitt Long OR, Parnassus ASC, Mount Zion OR, Orthopedic Institute, and Labor and Delivery). Any observed deficiency in the surgical sponge count policy and procedure is immediately addressed and referred to management for appropriate action. The results of the random observation audits were reported to the PSC on June 22, 2011 and again on July 20, 2011. As indicated, PSC identified appropriate measures necessary to implement risk reduction strategies and necessary follow-up actions by the	6/15/11 6/22/11 7/20/11

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	Continued From page 11 One thing I did not know was that they (nurses) have to scan the laps and raytex out before we start the count. My circulator (RN 1) and I both went on a relief break at the same time; that was a factor too. The nurses do the counts differently. Some allow the sponges to pile up in the ringstand, and others scan them immediately and put them in the bags. The policy says everything must be scanned before we count. The reason this happened is because we didn't follow the policy". The final interview was conducted on 6/30/11 at 3 p.m. with Physician 1. She told surveyors that, "I was notified that the counts were correct. I think it was RN 1 who told me at the time. I left to speak with the family and then went to the ICU to check on the patient. The fellow and the OR staff were discussing a possible retained sponge. The fellow told me; the OR staff did not communicate directly with me. I was told by the Nurse Manager Friday afternoon that there were still concerns about a retained sponge. Discussed it with a radiologist and ordered a CT (computerized tomography) scan". A 6/28/11 review of Patient 1's Operative Report for her second exploratory laparotomy on [redacted]11, electronically signed by the surgeon on [redacted]2011, indicated the following surgeon's note: "... This is an 85-year-old... who underwent an exploratory laparotomy...on [redacted]2011. At the end of the procedure I was verbally told that sponge, lap, and needle counters were correct x 2. The manual sponge count was correct; however, the scanned count was 1 lap sponge short. This was not told to the supervising team until the patient had been		department to ensure systemic compliance with the surgical sponge count policy and procedure. Additionally, beginning October 4, 2011, the Director of Perioperative Services provided monthly reports to QIEC for additional review and oversight, until the QIEC determines an alternative reporting period for such matters. PSC reports to QIEC. QIEC reports to EMB which in turn reports to GAC, the designated Governing Body. Lastly, the detailed and intensive interactive surgical sponge count competency assessments referenced in the Corrective Action section above enabled UCSF Medical Center to assess and monitor system-wide adherence by the perioperative department staff to the surgical sponge count policy and procedure.On July 22, 2011, perioperative leadership developed and implemented a prototype report generated by the SurgiCount scanner software as an additional objective measure of compliance with surgical sponge count policy and procedure.	10/4/11 and Ongoing 9/1/11 7/22/11

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	Continued From page 12 transferred to the ICU. A KUB (kidney, ureters, bladder x-ray) was obtained to rule out a retained foreign body, including a laparotomy sponge. It was read as negative by 2 radiologists. They continued to search for the missing sponge and the operative team had concerns that there was potentially a retained sponge at the end of the procedure. I was notified of this finding late on the afternoon of postoperative day number 1. At that time, the patient was in ICU and was not completely stable. She was requiring transfusion of blood products including fresh frozen plasma for a consumptive coagulopathy (blood clotting disorder) and required massive resuscitation with fluids. Given my concern as well as the ICU attendings, it was not felt that further imaging could be done at that time. After discussion with the radiology department, the plan was for a non-contrast (dye) CT to further assess for this retained sponge once she was stable. On postoperative day number 2, the patient was noted to be stable and had been extubated. We performed a non-contrast CT and the reading was notable for retained sponge likely in the right upper abdomen between the liver and the diaphragm...." The Intraoperative Findings documented in the Operative Report dated [redacted]11 indicated "Retained sponge between the liver edge and the right diaphragm". And, "It was also confirmed that her previous count had been incorrect by 1 lap sponge, which was found at the time of this surgery". A 6/28/11 review of the Medical Center Counts: Instruments, Sponges, Needles and Small Items policy and procedure (in effect at the time of the		This prototype report has been used in combination with interview, record review, and staff counseling when a variance in procedure was identified. Subsequently, the prototype report has been refined and the process systematized. Beginning September 29, 2011, ongoing SurgiCount Scanner reports that identify both incomplete scanner entries and manual entries by staff are actively reviewed and monitored weekly with feedback to and counseling of staff as indicated. Beginning October 4, 2011, the Director of Perioperative Services provided monthly SurgiCount Scanner reports to the OR Committee and to QIEC for additional review and oversight, until the QIEC determines an alternative reporting period for such matters. QIEC reports to EMB which in turn reports to GAC, the designated Governing Body.	9/29/11 10/4/11 and ongoing

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	Continued From page 13 current adverse event) noted the following processes: B. General counting process: 4. The initial and final counts must agree with the numbers on the dry erase board and the SurgiCount scanner and must be documented in the electronic case record. 14. Requests of any surgical team member to reconcile discrepancy or doubt must be honored. 15. The surgeon is informed of the results of all final counts conducted once all sponges are off the sterile field, scanned out and placed in the hanging counter bags. 16. An X-Ray is mandatory prior to leaving the OR on cases where: There is a sponge, needle, small item or instrument count discrepancy C. Sponge Counts: 5. Scanners and hanging sponge counter bag systems are used for all cases. 6. When a sponge counter bag is filled with 10 sponges, the scrub and circulator together will manually, audibly and visually count them. 10. Scan all sponges discarded from the sterile field ASAP, separating and scanning the data matrix tags individually. Then place sponges in hanging counter bags. Having the data matrix tag in plain view and facing outward is suggested. 12. Do not confirm final count is correct until all sponges are off the sterile field, scanned out and placed in hanging counter bag. 13. Confirm correct count when manual final count,		Responsible Party: Director, Perioperative Services; Chief Nursing Officer	

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	Continued From page 14 written count and electronic count are identical. 14. Do not count sponges from the rim of ring stand basin/kick bucket H. Procedures for Incorrect Counts: Any count discrepancy is treated as an incorrect count. When a discrepancy is identified the following steps are performed: 3. A visual and manual sweep of the operative site is conducted by MD to check for unintended retained items 5. The attending surgeon is notified immediately 6. If additional assistance is needed the circulating nurse notifies the charge nurse immediately. 7. In the event of the attending surgeon's departure prior to closing of the incision, he/she shall return to the operating room when notified of an incorrect count. 8. When a discrepancy cannot be reconciled, an x-ray is MANDATORY before the patient leaves the operating room. 9. The sterile field will be maintained until after confirmation that the wound is clear of sponges or instruments. References: Association of periOperative Registered Nurses (AORN) "Recommended Practices for Sponge, Sharp, and Instrument Counts-2011 Perioperative Standards and Recommended Practices" In addition, the nurses failed to act as advocates for Patient 1 when they "assumed the missing lap sponge was in the trash" and were not proactive with the surgical team to follow the protocols before			

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	Continued From page 15 they allowed her to be transported to the ICU. The facility's failure to implement it's sponge count policy resulted in the retention of a foreign body (laparotomy sponge) in Patient 1who had to undergo a second surgery to remove the retained sponge, and is a deficiency that has caused serious injury to the patiant, and therefore constitutes an immediate jeopardy within the meaning of 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).			

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