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
	050047	A. BUILDING _____ B. WING _____	04/19/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CALIFORNIA PACIFIC MEDICAL CENTER - PACIFIC	2333 Buchanan St, San Francisco, Ca 94115-1925 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: CA00263993 – Substantiated Representing the Department of Public Health: Surveyor ID# 14545, Health Facilities Eval. Nurse 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 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. This regulation was not as evidenced by:		Please note: The following constitutes California Pacific Medical Center's (CPMC) credible evidence of correction of the alleged efficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form CMS-2567 dated 4/19/11. Preparation and/or execution of this credible evidence submission does not constitute admission of agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies. The date of the exit conference is 8/4/2011. CA DEPT OF PUBLIC HEALTH APR 3 2012 L&C DIVISION SAN FRANCISCO	

Event ID: 04JH11 3/14/201 11:17:23AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Director, Risk Management TITLE (X6) DATE 3/30/2012

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POC accepted
4/4/12

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	Continued From page 1 Based on interview and record review, the facility failed to develop and implement surgical services policies in accordance with acceptable standards of practice when they failed to: 1. Develop and implement a surgical count policy that addressed how the staff would track the use of sponges used for packing in the wound. This deficient practice increased the risk of a retained surgical sponge as staff may forget to remove the packed sponges at the end of the case. The deficient practice resulted in a surgical sponge being left in Patient 1 who had to undergo a second surgical procedure to remove the retained foreign object. 2. Ensure all staff, including RN 1 completed required training on the new SurgiCount scanner system for counting sponges that the facility implemented on 7/19/11. RN 1 did not know the correct procedure for scanning in sponges during the initial count. 3. Include direct observation of staff proficiency in the count process in the operating room staff annual competency. The deficient practice limited the facility's ability to assess the proficiency of staff in the count process. Findings: Patient 1 was admitted to the facility on [redacted]/11 for bladder surgery and was discharged on [redacted]11. On [redacted]11, Patient 1 returned to the facility for a		Finding 1: **Corrective Action:** The Surgical Count Policy was revised to include a process for tracking sponges used for packing. The policy also limits the numbers of sponges remaining on the sterile field at the time of the final count. **Monitoring Process:** Surgical Services staff conducts observational audits to monitor compliance to the Count Policy and Procedure at each step of the process. Audit results are reported to the Quality Improvement Committee. **Responsible Persons:** Vice President, Surgical Services Surgical Services Directors and Managers. Finding 2: **Corrective Action:** All Surgical Services staff that scrub and circulate completed the required training for the Surgicount electronic counting system. RN 1 was re-trained and her competency validated. **Monitoring Process:** All Surgicount cases are audited. The audit data is reported and the manager of each Surgical Services area is responsible for reviewing the data and taking appropriate corrective action.	April 2011 Current and on-going 9/6/11 8/24/11 August 2011 and ongoing

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	Continued From page 2 routine post operative test (voiding cystourethrogram) which showed a possible retained sponge. A CT scan of the pelvis on [redacted]/11 indicated the following: Impression: 1. Retained surgical sponge marker in the right lower quadrant with a large associated presumed abscess cavity. The lower end of this radiopaque marker was localized and marked externally on the patient's skin for potential surgery. Patient 1 was taken back to the operating room on [redacted]/11 for surgery to remove the retained surgical sponge. On 8/2/11 at 9:40 a.m., Patient 1's intraoperative record dated [redacted]11 was reviewed and showed that the initial, closing and final sponge counts were documented as correct. There was a consent for surgery signed by the patient on [redacted]11 that listed the procedure as "Exploratory laparotomy removal of foreign body." Patient 1's operative note dated [redacted]11 indicated a pre and post operative diagnosis of retained foreign body. The name of the procedure was listed as "Abdominal exploration, removal of a retained foreign body, abdominal irrigation. " The description of the procedure included the following: "As one progressively mobilized this area, which on CT scan had shown to be the area of the retained abdominal laparotomy pad, a plane was dissected in the right lateral aspect and entry made into a pocket from which purulent material drained. A specimen was collected for laboratory evaluation		**Responsible Persons:** Vice President, Surgical Services Surgical Services Directors and Managers Finding 3: **Corrective Action:** The RN Competency Based Evaluation (CBE) for nurses working in the Operating Room was revised to include competencies specific to the safety of the surgical patient. The competency for Surgical counts is evaluated through multiple modalities, including direct observation. **Monitoring Process:** The CBE is a part of the annual performance evaluation for each RN. Each manager / director is expected to complete 100% of employee performance reviews on time. **Responsible Persons:** Vice President, Surgical Services Surgical Services Directors and Managers CA DEPT OF PUBLIC HEALTH APR 3 2012 L&C DIVISION SAN FRANCISCO	8/2011 All annual RN reviews were completed in November 2011 according to hospital policy.

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and the rest progressively suctioned. With further dissection, a cavity was entered within which was the abdominal lap pad. This was gently and carefully removed with care not to damage the wall of the cavity which appeared to be small intestine. The cavity was thoroughly irrigated as was the abdominal cavity with 4 L (liters) of bacitracin solution."

During an interview on 8/2/11 at 3:10 p.m., the SDDSS (senior director department of surgical services) stated she first became aware of the retained surgical sponge when the surgeon called the charge nurse to schedule the procedure to remove the retained sponge. She said the facility conducted an RCA (root cause analysis) to determine the cause of the retained sponge but "Couldn't come up with anything." She stated the sponge left in Patient 1 could have been a sponge that was used to pack the wound during surgery.

The SDDSS stated she reviewed the counts policy with the staff involved and "They followed the policy." The SDDSS was asked if she could explain how the staff followed the policy and a sponge was still left in Patient 1, She said "The staff made a mistake in counting."

She said there was "difficulty" in getting all the sponges in the counter bags for the final count and that the policy in effect at the time of the retained sponge, did not require all sponges be in the counter bags for the final count.

On 8/3/11 at 9:40 a.m., ST (Surgical Technician) 1

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was interviewed and stated he did the closing and final count with RN 1 during Patient 1's surgery. He said he and RN 1 conducted the closing sponge count by first counting the sponges at the incision and then moving to the Mayo table, the back table and sponge counter bags. He said there were "quite a few" sponges left on the sterile field during the closing count. He stated during the final count all the sponges were counted again in the same order and the count was correct. When asked how a sponge was left in Patient 1, he responded "I can't explain it, I don't know." He also said that during Patient 1's surgery there was no process in place to track sponges that were packed in the wound. He s aid "At that time I just kept an eye on it."

On 8/3/11 at 10:10 a.m., RN 1 was interviewed and stated she was the circulating nurse for Patient 1's first surgery on [redacted]11. She said she did the closing and final counts with ST 1. She said she couldn't remember how many sponges were on the field during the closing and final count but most surgical technicians keep a couple on the Mayo stand. RN 1 stated "The count was correct, I don't know how it could have happened."

A review of the facility's Counts policy and procedure (revised 1/11) which was in effect during Patient 1's surgery on [redacted]11 indicated the following:
B. Sponge Counts
1.r. Final and Closure count: Circulator and scrub count the sponges on field, surgical site, immediate surrounding area, mayo, back table, and sponges

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	Continued From page 5 in any partially filled bags. The circulator then exposes the previously counted bags to the scrub in order to reconcile the total number documented on the count board/sheet. 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 Surgeons, American Society of Anesthesiologists and the American Association of Ambulatory Surgery Centers. The AORN position papers, standards 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 Practices, pg. 263, "Retained objects are considered a preventable occurrence. Many states require public reporting when these events occur. Federal and state agencies, accrediting bodies, third-party payers, and professional associations consider an RSI (retained surgical item) a sentinel event or "never event."... Recommended Practices for Prevention of Retained Surgical Items. Recommendation I (pg. 264 &265). A consistent multidisciplinary approach for preventing RSI's should be used during all surgical and invasive procedures. Retained surgical items are preventable events that		CA DEPT OF PUBLIC HEALTH APR 3 2012 L&C DIVISION SAN FRANCISCO	

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can be reduced by implementing multidisciplinary system and team interventions. Retained surgical items may result in morbidity and mortality for the patient and prove costly to health care organizations. Establishing a system that accounts for all surgical items opened and used during a procedure constitutes a primary and proactive injury-prevention strategy. Performing surgical item counts is one RSI-prevention strategy. Accounting systems that involve counting and detection are, at a minimum, team based activities composed of input from multiple team members. The practices employed should be standardized, transparent, verifiable, and reliable. All items need to be accounted for at the end of a procedure so that all team members can be sure that a surgical item is not left in the patient.

I.a. All perioperative team members should be responsible for the prevention of RSIs.

I.d.1. The surgeon(s) and surgical first assistant(s) should maintain awareness of all soft goods, instruments used in the surgical wound during the course of the procedure. The surgeon does not perform the count but should facilitate the count process by

... communicating placement of surgical items in the wound to the perioperative team for notation (e.g., whiteboard) ... performing a methodical wound exploration when closing counts are initiated.

Recommendation II (pg. 266, 267 & 268).
Radiopaque surgical soft goods (e.g., sponges, towels, textiles) opened onto the sterile field should

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be accounted for during all procedures for which soft goods are used.

Accurately accounting for radiopaque sponges throughout the surgical procedure should be a priority and requires a multidisciplinary effort.

II.b. Counts of soft goods should be performed ...

-when wound closure begins:

-at skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (i.e., final count); and...

II.h. The final count should not be considered complete until all sponges used in closing the wound are removed from the wound and returned to the scrub person. Sponges used in closing the wound could be left in the wound.

Doctor Verna Gibbs, director of the surgical patient project "No Thing Left Behind" (an organization dedicated to the prevention of retained surgical items-www.nothingleftbehind.org) states "The single most important element in the use of the hanging sponge holders and the sponge Accounting system is to make sure that the final count is taken when ALL the sponges that have been opened during the case (used and unused) have been placed in the holders."

A O R N C o n n e c t i o n s (www.aorn.org.News/February2010News/Counts) indicates the following regarding the roles of the surgical team during the count process:

Nurses

-Closing count: While the surgeon does the wound

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exam, perform a focused 2-person count, using the sponge holders to get the sponges in one place. ...

-Final count-Performed before the patient leaves the OR. Verify that all sponges (used and unused) are in the hanging sponge holders.

2. During an interview on 8/2/11 at 3:10 a.m., the SDDSS stated the facility had implemented a new system to help prevent retained surgical sponges. The SurgiCount scanner (a device that is used to scan in and out all sponges used during surgery and alerts the user if a sponge that was scanned in was not scanned out) was implemented at the facility on 7/19/11. She stated all staff using the scanner had received hands on training from the vendor and were required to complete an online module which included the facility's updated counts policy and how to used the SurgiCount scanner.

A review of the facility's Assignment Completion Report (data as of 8/2/11) on 8/2/11 indicated only 74.51% of the staff had completed the online module regarding the SurgiCount scanner. The module included a review of the facility's updated policy to include the SurgiCount scanner and a post test. The module which had a due date of 7/11/11 had not been completed by 12 staff members including RN 1.

RN 1 was interviewed on 8/3/11 at 10:10 a.m. She was asked to describe how she would do an initial count using the SurgiCount scanner system. She stated after entering required data in the scanner, she would unwrap a pack of sponges and while holding them in the sterile pack she would scan the

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sponges in and pass them to the scrub technician who would break the band on the sponges. Then she and the scrub would count the sponges while the scrub separated them. RN 1 was asked when she completed the online module and responded "I did it last night (8/2/11)."

The facility's policy specifies that during the initial sponge count the scrub technician holds the sponges while the circulating nurse uses the scanner (positioned a safe distance from the sterile field) to scan in the sponges. This ensures the sterility of the sponges being scanned in and decreases the risk of mistakes by having all staff follow the same procedure.

During an interview on 8/3/11 at 3 p.m., the SDDSS stated that all staff had received hands on training from the vendors regarding the SurgiCount scanner. She acknowledged that not all staff had completed the online module but said "There are different ways to train, multiple modalities." Admin. Staff A who was present during the interview stated that all staff who were scheduled to work today (8/3/11) had completed the online training "as of today."

According to 2011 AORN Perioperative Standards and Recommended Practices,

Recommended Practices for Prevention of Retained Surgical Items.

Recommendation I (pg. 264 & 265).

A consistent multidisciplinary approach for preventing RSI's should be used during all surgical and invasive procedures.

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	Continued From page 10 I.e. The scrub person and the RN circulator should perform standardized procedures when accounting for all surgical items opened or used during a procedure as required by the health care organization's policy. Reason's study of human error has shown that errors involve some kind of deviation from routine practice. Deliberate, consistent application and adherence to standardized procedures are necessary to prevent the retention of surgical items. Recommendation VII (pg. 274 & 275). Perioperative staff members may consider the use of adjunct technologies to supplement manual count procedures. VII.b.1. Perioperative personnel should be aware of and competent in the proper use and application of adjunct technologies if used within the health care organization. Technological systems are dependent on proper usage and technique. 3. During an interview on 8 /3/11 at 3:30 p.m., the OR Manager was asked how the facility ensures the staff are competent in the count process and are following the facility's count policy and procedure. She said the charge nurses do rounds and observe the staff. She stated "We rely on the staff to tell u s if other staff members are not following the count policy and procedure. The expectation is they will follow the policy and procedure." The OR Manager said the staff annual competency included an online review of the count policy and procedure. When asked is any direct observation of staff proficiency in the count process			

ABORATORY 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
	050047	A. BUILDING _____ B. WING _____	04/19/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CALIFORNIA PACIFIC MEDICAL CENTER - PACIFIC	2333 Buchanan St, San Francisco, Ca 94115-1925 SAN FRANCISCO COUNTY

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Continued From page 11

was done on an annual basis, she responded " I'm not sure if my educator has done that type of observation."

A review of the facility's 2009-2010 Performance Review for RN 1 indicated competencies that included "Cultural Competence/Diversity, Infection Control, Patient Rights, and Service and Satisfaction." The count process was not included in the facility's annual performance review.

The SDDSS who was present during the review stated that the form used in 2007 and 2008 had included the count process as part of the annual competency for operating room staff. She said the performance review form used by the facility now was not as specific and the facility was in the process of changing the form to include the count process. She stated "I don't know why the form was changed."

The facility's Counts policy and procedure (revised 1/11) which was in effect during Patient 1's surgery on [redacted]/11 was reviewed and 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.

According to 2011 AORN Perioperative Standards and Recommended Practices,

Recommended Practices for Prevention of Retained Surgical Items.

Recommendation X (pg. 276 & 277).

Policies and procedures for the prevention of RSIs and unretrieved device fragments should be

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	Continued From page 12 developed, reviewed periodically, revised as necessary, and readily available in the practice setting. X.a. A multidisciplinary team should establish a policy and procedure for prevention of RSIs. These policies and procedures should include, but not be limited to, - competency validation. The facility failed to develop and implement a surgical count policy that specified that all surgical sponges (used and unused) be placed in the sponge counter bags prior to the final count and that surgical sponges used as packing in the surgical wound be documented on the white board, failed to ensure all staff, including RN 1 completed required training on the new SurgiCount scanner system for counting sponges that the facility implemented on 7/19/11 and failed to include direct observation of staff proficiency in the count process in the operating room staff annual competency. 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 of Health and Safety Code section 1280.1			

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