

California Department of Public Health

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br><b>CA220000022</b> | (2) MULTIPLE CONSTRUCTION<br>A. BUILDING _____<br>B. WING _____ | (3) DATE SURVEY COMPLETED<br><br>C<br><b>11/17/2009</b> |
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| NAME OF PROVIDER OR SUPPLIER<br><br><b>CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC</b> | STREET ADDRESS, CITY, STATE, ZIP CODE<br><b>2333 BUCHANAN STREET<br/>SAN FRANCISCO, CA 94115</b> |
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**E 000** The following represent the findings of the California Department of Public Health during an investigation of Entity Reported Event #CAO0191275 regarding retained foreign object during surgery. The investigation of the reported event was substantiated.

The inspection was limited to the specific reported event investigated, and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

██████████ R.N., Health Facilities Evaluator Nurse  
██████████, R.N., Health facilities Evaluator Nurse

Health and Safety Code Section 1280.1(c):

For purposes of this section, "immediate jeopardy" means a situation in which the licensee's non-compliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

**E 000** **Please Note:**  
The following constitutes California Pacific Medical Center (CPMC) – Pacific Campus Hospital's credible evidence of correction of all of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form CMS- 2567 dated 11/17/09. Preparation and/or execution of this credible evidence submission does not constitute admission or agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies.

The Statement of Deficiencies form is dated 11/17/09, however the hospital records indicate the survey was completed on 11/18/09 by Andrea Kubovicik, RN and Alice Morrissey, RN.

**E 264** T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures.

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

This Statute is not met as evidenced by:

**E 264** E 264, E 269, E 271

**Corrective Action:**

Failure to comply with the established Surgical Count policy has been addressed with the staff involved in this event.

6/09

Licensing and certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

*Alice Caray*

*Director, Risk Management*

(6) DATE

*02/15/10*

STATE FORM

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**CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**

continuation sheet 1 of 10

APR 29 2010

L & C DIVISION  
DALY CITY

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| E 269              | Continued From page 1  | E 269         | E 264, E 269, E 271 cont.  |                      |
| E 269              | <p>T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures.</p> <p>(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, a circumstances require, patient advocacy.</p> <p>This Statute is not met as evidenced by:</p>  | E 269         | <p>The Surgical Services Policy # 27.2.1.54, "Counts, Surgical" has been revised to state:</p> <p>"General Rules:</p> <p>2. The count process requires <u>vigilance and continual readiness to account for required items included in a surgical count.</u> Every effort should be made throughout the procedure to be ready to perform a count at any time.</p> <p>3. OR staff will initiate the chain of command when faced with resistance by any member of the surgical team to comply with the surgical count policy.</p>   | 12/18/09             |
| E 271              | <p>T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.</p> <p>(d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.</p> <p>This Statute is not met as evidenced by: Based on interview and record review, hospital failed to implement its Surgical Counts policy and procedure when RN 1/CVC (cardiovascular charge nurse) added a retractor and blades to the surgical field without counting them, and failed to document the addition of the retractor and blades on the instrument count sheet. The hospital failed to orient staff to instruments being used in surgery and failed to implement its Vendors and Sales Representatives policy and procedure when a retractor and blades were brought to the facility the day of surgery instead of 16 to 24 hours prior to the surgery. This resulted in a</p> | E 271         | <p>The "Counts, Surgical" policy was revised to include standardization of count boards and count sheets as well as the process for documenting onto the boards and sheets.</p> <p>There is also a record to document the count for extra instrument sets, i.e. instruments brought in by a vendor or surgeon.</p> <p>In addition, "Surgical Services Handoff Guidelines" were implemented to improve critical communication elements in the OR, i.e. sponges, sharps, medications, specimens. Recommended Relief Rules were also established in an effort to reduce the number of relief breaks that may occur during a case.</p> |                      |

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| E 271 | <p>Continued From page 2</p> <p>retractor blade having been left in Patient 1 who had to undergo a second surgical procedure to remove the retained foreign object.</p> <p>Findings:</p> <p>1. Patient 1 was admitted to the hospital on 4/14/09 for mitral valve repair and was discharged on 4/18/09. In June 2009, the patient was experiencing chest pain and was seen by her cardiologist in her home state. A subsequent chest x-ray and ultrasound determined the presence of a a metal plate in her chest area. Patient 1 was readmitted to the facility on 6/22/09 and on 6/23/09 had surgery to remove a retained retractor blade.</p> <p>On 11/16/09 at 10:50 a.m., Patient 1's intraoperative record dated 4/14/09 was reviewed, and indicated that the initial, closing and final instrument counts were documented as correct.</p> <p>There was an intraoperative report dated 6/23/09 which listed the surgical procedure as "Removal Retained Foreign Object."</p> <p>Patient 1's operative note dated 6/23/09 noted a pre and post operative diagnosis of retained foreign object. The surgeon documented that he had repaired Patient 1's mitral valve a few months ago and, "That part of the operation was successful. It required some additional retractors, however, that were brought in from the outside and these were not properly accounted for at the end of the operation and she ended up with a retractor blade lined posteriorly in her thorax that we did not recognize during her stay in the hospital. Therefore she was brought back to have it be removed."</p> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>CPMC Administrative Policy 2.98, "Universal Protocol" states:</p> <p>J. "Time Out" before starting the Procedure:</p> <ol style="list-style-type: none"> <li>"Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure.</li> <li>Members of the care team are <b>expected to speak up immediately and stop the process</b> if they notice any discrepancy or believe any step in the safety check process is missed or incomplete.</li> </ol> <p>K. Sign Out:</p> <ol style="list-style-type: none"> <li>Prior to leaving the procedure area, the RN verbally confirms with the team... <ul style="list-style-type: none"> <li>Instruments, sponge and needle counts are correct</li> <li>Equipment problems to be addressed</li> </ul> </li> </ol> <p>Staff education for the "Universal Protocol" was provided during Surgical Services education meetings.</p> <p>Surgical Services Policy 27.3.0.11, "Vendors and Sales Representatives; Special Instruments/Equipment/Supplies Guidelines in the Surgical Services Department" has been revised to state:</p> | <p>Current as of 11/19/09</p> <p>12/18/09</p> |
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| E 271   | <p>Continued From page 3</p> <p>On 11/16/09 at 3:25 p.m., RN 2 was interviewed. She stated she was the scrub nurse for Patient 1's first surgery on 4/14/09. She said she was unfamiliar with the approach being used by the surgeon and that she made RN 1/CVC aware of this prior to the procedure. RN 2 said "(name of circulating nurse) and I had never done that type of case, the approach was different, RN 1/CVC was there to guide us." She stated that Surgeon 1 works very quickly. She said, "I've never worked with anyone who goes that fast." RN 2 stated the retractor and blades were brought into the operating room after the initial count had been done and after Patient 1's chest had been opened. She stated "It was the middle of the case." She said "I'd never seen these instruments or used them before." She said that Surgeon 1 wanted the retractor and blades immediately. The retractor vendor was in the operating room to answer any questions the surgeon may have had about the product. When asked if the retractor and blades were counted, she stated "I eyeballed it, but myself and the circulator didn't get time to count them. I felt pressured and I didn't get time to count." She added "It was a hectic environment, the noise level was very high."</p> <p>RN 1/CVC was interviewed on 11/16/09 at 3:45 p.m. She stated she was the charge nurse of cardiovascular services and what happened was "an unfortunate event." She said that Patient 1's procedure was "entirely different to what he (Surgeon 1) usually does." She stated that a vendors representative brought the retractor and blades to the facility the morning of Patient 1's surgery, that she (RN 1) flash sterilized the instruments, brought them into the operating room and put them on the instrument table. When asked if the retractor and blades were counted, she responded "I guess that was not</p> | E 271  | <p>E 264, E 269, E 271 cont.</p> <p>3. a. New products, instrument systems, implants or equipment requests are approved through the following methods as appropriate: Value Analysis Committee, New Technology Committee, and/or the department chair/designee.</p> <p>b. <u>The operating room manager/designee will ensure that the items requested are approved.</u></p> <p>c. Approved new products and evaluations of products will be communicated through a bulletin from the Value Analysis Committee.</p> <p>d. <u>The confirmation of approved vendor instrument systems/equipment, will be communicated to the staff by utilizing the Vendor Audit Tool which will follow the instruments/equipment throughout the process.</u> The tracking tool will start at the receiving unit and end when the procedure is completed.</p> <p>e. Manager/designee and Materials Management Staff will establish a plan for contacting the vendor. The designated person will make arrangement for timely delivery of the equipment/implants required for the procedure.</p> <p>f. Manager/Supervisor/Service Leader or designee will arrange for staff education with the vendor prior to using new or unfamiliar instruments or equipment.</p> <p>D. Sterile Processing</p> <p>4. Pre-procedure sets will arrive ideally 8 to 24 hours prior to the start of a scheduled elective procedure.</p> <p>a. Instruments/implant sets must be inspected, cleaned, decontaminated, and sterilized by CPMC staff prior to patient use.</p> <p>b. Electrical equipment must be checked by Biomedical Engineering before use on any CPMC patient.</p> |  |

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| E 271 | <p>Continued From page 4</p> <p>done. I'm sure I counted the pieces but I can't remember specifically but that's my usual practice." When asked if she documented counting the instruments, she said "I didn't write it down."</p> <p>RN 1/CVC was asked when the retractor and blades were brought into the operating room. She stated "I brought it into the operating room after the procedure started. ( Name of RN 2) was right up there, maybe she didn't have a chance to come away from the table to count." RN 1/CVC said "(Name of RN 2) was unfamiliar with the instruments, she was on the other side of the table, she probably couldn't even see when he (Surgeon 1) took out the retractor." RN 1/CVC added" I assumed that everyone knew what to do with the retractor."</p> <p>When asked how the retractor blade was left in Patient 1, RN 1/CVC responded" He (Surgeon 1) must have just unscrewed it and left it fall into the wound. I can't believe he did that." She stated that when the surgery was finished, the retractor and blades were sent downstairs to the SPD (sterile processing department) for sterilizing. She said when the vendor picked up the instruments, he noticed that a blade was missing but he never notified the facility.</p> <p>RN 3 was interviewed on 11/17/09 at 10:30 a.m. She stated she was assigned to be the circulating nurse for Patient 1's procedure on 4/14/09. She said she was not familiar with the approach being used by Surgeon 1 so she notified her senior nurse (RN 1/CVC). She stated that RN 1/CVC was the primary circulating nurse for the procedure as she (RN 3) was going between two operating rooms. RN 3 stated she did the closing and final count with RN 2 and the retractor and blades were not listed on the count sheets. She</p> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>5. b. <u>An inventory list will be completed for instrument sets used on procedures where an instrument count is required. If the vendor is unable to provide this, the department receiving the set (OR or SPD) will complete an inventory /count list.</u></p> <p>9. Inventory lists are affixed to or included with instrument sets used on procedures where an instrument count is required.</p> <p>F. Operating Room:</p> <p>6. The circulating RN will:</p> <ul style="list-style-type: none"> <li>▪ Confirm that the product, instrument, or implants have been approved for use by CPMC</li> <li>▪ Confirm prior to the start of the procedure that the loaner instruments have been processed at CPMC,</li> <li>▪ <u>Confirm that a count sheet is included if the procedure requires an instrument count by policy.</u></li> <li>▪ <u>Confirm that the staff have received education.</u></li> </ul> <p>Surgical Services staff has been informed of the changes to the policy and are aware of their responsibilities.</p> <p><b>Monitoring Process:</b><br/>The Surgical Services staff is completing concurrent monitoring of the count process including compliance to general rules, initial count, handoff process and closing counts. Monitoring results will be reported to the Surgery and Operating Room Committee and the hospital Quality Improvement Committee.</p> | <p>12/18/09</p> <p>Current and ongoing</p> |
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| E 271 | <p>Continued From page 5</p> <p>said" I never saw that retractor that day."</p> <p>The facility's Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated the following:<br/>Policy:<br/>Surgical counts will be performed utilizing the following guidelines. The use of a standardized systematic method of accounting for instruments, sponges, needles and specific small items used during a surgical procedure will promote patient safety by helping to prevent retained foreign bodies.</p> <p>A. General Rules.</p> <ol style="list-style-type: none"> <li>1. It is the responsibility of all members of the surgical team to maintain an optimal Operating Room environment to allow focused performance of operative tasks. Distractions and interruptions should be kept to a minimum during the count.</li> <li>2. Counts are performed following the guidelines for the category of the items counted.</li> <li>4. Counts are to be performed by two people, the circulating Registered Nurse (RN), and a scrub person. The circulating RN is responsible for conducting the counts and must be a participant of every count.</li> <li>5, The items are counted audibly, and concurrently viewed by the scrub person and circulating RN.</li> <li>12. Sponge types, free needles, atraumatic needles, sharps, and miscellaneous items are recorded separately on the standardized preformatted whiteboard. A preformatted work sheet mirroring the whiteboard is used when a whiteboard is not accessible. Instruments are recorded on standardized count sheets.</li> <li>13. A running total of needles, sharps, and miscellaneous items are placed on the boards,</li> </ol> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>A monitoring audit tool for vendors, with associated indicators, has been developed.</p> <p>The monitoring is conducted by surgical services staff concurrently on all vendor cases. The audit data is reported quarterly to Surgical and Operating Room Committee and to the Quality Improvement Committee.</p> <p>All vendor products that arrive less than 8 hours prior to surgery, regardless of reason, will be tracked and reviewed for system issues and common factors and will be included in the report.</p> <p>The Surgical Services Count and Vendor policies and monitoring tools are attached for your reference.</p> <p><b>Responsible Persons:</b></p> <p>Senior Director, Surgical Services and Director, Outcomes Management</p> | Current and ongoing |
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| E 271   | <p>Continued From page 6</p> <p>worksheets, and instrument count sheets will be done as items are added. The method of documenting additions and totals is standardized.</p> <p>20. When counts are performed: Instruments</p> <p>b. As new counted items are added to the field.</p> <p>D. Instrument Counts.</p> <p>1. Instrument counts are performed on all procedures involving, or reasonably anticipated to involve, the opening of a major body cavity such as:</p> <p>d. the pleural/thoracic cavity.</p> <p>3. Initial instrument count is performed following the order on the standardized count sheet.</p> <p>4. Use this standardized count sheet to document instruments added during the procedure.</p> <p>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.</p> <p>According to 2008 AORN Perioperative Standards and Recommended Practices, pg. 293, "Retained objects are considered a preventable occurrence, and careful counting and documentation can significantly reduce, if not eliminate, these incidents."</p> <p>Recommended Practices for Sponge, Sharp, and</p> | E 271  |   |

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| E 271   | <p>Continued From page 7</p> <p>Instrument Counts.<br/>Recommendation 111 (pg. 296).<br/>Instruments should be counted for all procedures in which the likelihood exists that an instrument could be retained.</p> <p>2. Instruments should be counted audibly and viewed concurrently by two individuals, one of whom should be a registered nurse circulator. Concurrent verification of counts by two individuals assists in ensuring accurate counts.</p> <p>6. When additional instruments are added to the field, they should be counted when added and recorded as part of the count documentation.</p> <p>The facility failed to implement its Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure when RN 1/CVC added a retractor and blades to the surgical field and failed to initiate an instrument count. RN 1/CVC also failed to document the addition of the retractor and blades on the instrument count sheet.</p> <p>The Director of Perioperative Services was interviewed on 11/17/09 at 2:30 p.m. and said "the vendor policy was not followed." She stated that Surgeon 1 had contacted the vendor to bring in the retractor and blades for Patient 1's surgery. The vendor brought in the instruments the morning of Patient 1's surgery and they were flash sterilized.</p> <p>The facility's Vendors and Sales Representatives: Guidelines in the Surgical Services Department policy and procedure was reviewed and revealed the following:<br/>D. Sterile Processing Departments<br/>4. Pre-Procedure:</p> | E 271  |   |  |



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| E 271   | <p>Continued From page 8</p> <p>Sets must arrive at least 16 to 24 hours prior to the start of a scheduled elective procedure. (Instrument sets cannot be wrapped, processed and sterilized in less than three hours from receipt of product).</p> <p>7. The SPD (sterile processing department) staff will inspect all trays and process them in a washer/decontaminator or hand wash them if required.</p> <p>8. SPD staff will wrap and sterilize the trays and place them onto a separate cart/area to be sent to the O.R. on the evening before or the morning of the procedure.</p> <p>The 2008 AORN Recommended Practices for Sterilization in the Perioperative Practice Setting, pg.578 &amp; pg.579 indicates the following:<br/>Recommendation IV</p> <p>Use of flash sterilization should be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner.</p> <p>Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process.</p> <p>According to 2008 AORN Perioperative Standards and Recommended Practices, p.181, AORN Guidance Statement: The Role of the Health Care Industry Representative in the Perioperative Setting, "Perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment before their use in a surgical procedure. This instruction may be provided by a health care industry representative and may take place in a formal inservice program or as a</p> | E 271  | <p>E 271 cont.</p> <p><b>Corrective Action:</b></p> <p>CPMC Surgical Services Policy and Procedure 27.3.0.8 "Flash Sterilization in the Operating Room" defines flash sterilization "as the sterilization of unwrapped items with the use of saturated steam under pressure in a gravity displacement or pre-vacuum sterilizer. Saturated steam under pressure should be used to sterilize heat and moisture-stable items". The policy and procedure references the AORN 2008 Standards of Practice.</p> <p>The Procedure specifies:</p> <ol style="list-style-type: none"> <li>4. Specialty instruments or devices are sterilized according to the manufacturer's recommendations/instructions.</li> <li>9. Prior to removing the item from the autoclave, the person removing the item is responsible for examining the graph/digital autoclave printer tape to ensure that the correct time, temperature, and pressure have been met.</li> <li>10. Upon removing the item from the sterilizer, and again prior to placing the item on the sterile field, examine the chemical indicator for changes.</li> </ol> <p><b>Both the scrub and circulating staff (or other staff opening the autoclave) are responsible for examining the indicators for change, indicating that sterilization parameters have been met.</b></p> | Complete as of 11/19/09 |

California Department of Public Health

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| E 271   | <p>Continued From page 9</p> <p>one-on-one instruction. The facility should maintain evidence of documented competencies for perioperative team members, especially when introducing new procedures, techniques, technology, and equipment.</p> <p>The facility failed to implement its Vendors and Sales Representatives: Guidelines in the Surgical Services Department policy and procedure when the instruments for Patient 1's surgery were brought to the facility the morning of the procedure instead of at least 16 to 24 hours prior to the start of the procedure. This resulted in the instruments being flash sterilized and RN 2 and RN 3 being unfamiliar with the retractor and blades being used during Patient 1's surgery. RN 2 and RN 3 were also unfamiliar with the surgical approach being used by Surgeon 1 during Patient 1's surgery.</p> <p>This failure is a deficiency that has 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.</p> | E 271  | <p>E 271 cont.</p> <p><b>Monitoring Results:</b></p> <p>For every load sterilized, the staff record the patient information, type of case, and items sterilized. This information is reviewed along with the autoclave records.</p> <p>The data is summarized in a Quality Monitoring Report and submitted quarterly to the CPMC Infection Control Committee.</p> <p>A copy of the Flash Sterilization Policy is attached for reference and review.</p> <p><b>Responsible Person:</b></p> <p>Senior Director Surgical Services<br/>Manager, Infection Control</p> <p><b>CALIFORNIA DEPARTMENT<br/>OF PUBLIC HEALTH<br/>APR 29 2010<br/>L &amp; C DIVISION<br/>DALY CITY</b></p> | Current and ongoing  |

California Department of Public Health

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**E 000** Initial Comments

The following represent the findings of the California Department of Public Health during an investigation of Entity Reported Event #CAOO198637 regarding retention of a foreign object during surgery. The investigation of the reported event was substantiated.

The inspection was limited to the specific reported event investigated, and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

Andrea Kubovcik, RN, Health Facilities Evaluator Nurse

Health and Safety Code Section 1280.1(c):

For purpose 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.

**E 264** T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures.

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

This Statute is not met as evidenced by:

**E 269** T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures.

**E 000** **Please Note:**  
The following constitutes California Pacific Medical Center (CPMC) – Pacific Campus Hospital's credible evidence of correction of all of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form CMS-2567 dated 11/18/09. Preparation and/or execution of this credible evidence submission does not constitute admission or agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies.

**E 264** E 264, E 269, E 271

**Corrective Action:**

The Surgical Services Policy # 27.2.1.54, "Counts, Surgical" has been revised to include the use of sponge pocketed holding bags.

B. Sponge counts:

15. Separate and unfold all sponges prior to placing in the counter bag pockets.
16. Once the bags are full, the sponges are counted audibly and concurrently, viewed by the scrub person and the circulating RN. An empty bag is then placed on top of the counted filled.

Complete as of 12/18/09

**CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**  
**APR 29 2010**  
**L & C DIVISION DALY CITY**

Licensing and certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

*Shirley Carney*

*Simbar, Rick* TITLE

(5) DATE

*02/15/10*

*copy to public file - 5/19/10*

*Yoshida 9/24/10*

California Department of Public Health

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| E 269              | Continued From page 1<br><br>(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.<br><br>This Statute is not met as evidenced by:  | E 269         | E 264, E 269, E 271 cont.<br><br>17. Final and closure counts... the Circulator then exposes the previously counted bags to the scrub in order to reconcile the total number documented on the count board/sheet.<br><br>The policy and procedure includes "Guidelines on using Sponge Bags".   |                      |
| E 271              | T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.<br><br>(d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.<br><br>This Statute is not met as evidenced by:<br>Based on interview and record review, the hospital failed to develop a surgical count policy that mandated that bagged surgical sponges be recounted during the final count. This resulted in a surgical sponge having been retained in Patient 2, who was forced to undergo a second surgical procedure to remove the retained foreign object.<br><br>Findings:<br><br>1. Patient 2 was admitted to the hospital on 7/9/09, and on 7/15/09 had a sigmoid colon resection, repair of colovesical fistula and colorectal anastomosis. Patient 2 had a history of hypertension, chronic obstructive pulmonary | E 271         | <b>Monitoring Process:</b><br><br>Surgical Services staff complete concurrent audits in order to ensure compliance to the Count Policy and Procedure at each step of the process.<br><br>The monitoring results are reported to the Surgical and Operating Room Committee and the hospital wide Quality Improvement Committee.<br><br><b>Responsible Persons:</b><br><br>Senior Director Surgical Services and Director, Outcomes Management<br><br>The Surgical Services Count Policy and Procedure, count forms and audit tool are attached for reference and review. | Current and ongoing  |

California Department of Public Health

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| E 271   | <p>Continued From page 2</p> <p>disease and underwent kidney transplant surgery in 2007. On 7/29/09, he was discharged from the facility. In August 2009, Patient 2 was seen at an outside facility for recurrent fevers, abdominal pain and pneumaturia. Tests done at the outside facility determined the presence of a retained foreign body in his abdominal cavity. Patient 2 was transferred back to the hospital on 8/11/09 and on 8/13/09 he had surgery that included the removal of a surgical sponge retained in his right upper quadrant.</p> <p>On 11/16/09 at 11: 1 0 a.m., Patient 2's intraoperative case record dated 7/15/09 was reviewed, and revealed that the initial, closing, and final sponge counts were documented as correct. There was an intraoperative case record dated 8/13/09 which listed the surgical procedure as revision of colorectal anastomosis, takedown of colovesical fistula, diverting loop ileostomy and removal of retained foreign object.</p> <p>Patient 2's operative note dated 8/13/09 indicated a pre and post operative diagnosis of recurrent colovesical fistula and possible foreign body. The name of the procedure included "removal of right upper quadrant foreign body." The description of the procedure included the following: "Attention was first paid to the possible right upper quadrant mass. There was a large area of matted bowel in the right upper quadrant. Careful palpation was able to free this wad of bowel from the retroperitoneum and the colonic mesentery. It was entirely composed of small bowel. The adhesions between loops of bowel were carefully dissected free using Metzenbaum scissors. As the center of this wad of bowel was reached, some pus was visualized and suctioned out and sent for culture. The intraloop adhesions were dissected free very carefully over a period of time,</p> | E 271  |   |                      |

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| E 271   | <p>Continued From page 3</p> <p>taking care not to injure the bowel. In the course of this, the foreign body was visualized and carefully brought out from between the bowel using a combination of blunt and sharp dissection. This was passed off the field."</p> <p>On 11/16/09 at 1:50 p.m., RN 4 was interviewed and stated she was the circulating nurse for Patient 2's first surgery on 7/15/09. She stated she did the initial count with a registered nurse who no longer works at the facility and the closing and final count with ST 1 (surgical technician). RN 4 was asked to describe how the surgical sponges were counted during Patient 1's surgery. She said when surgical sponges were removed from the surgical field during the surgery, she would "count off five, show them to the scrub, then bag them." When asked if the bagged sponges were recounted during the final count, she responded "No, we don't open the bags, we just count each bag and assume it contains five sponges."</p> <p>ST 1 was interviewed on 11/16/09 at 2:25 p.m. He stated that surgical sponges used during Patient 2's surgery were discarded into a bucket, the circulating nurse counted off five, showed them to him and "wrapped them up." He said the bags of sponges were not opened and recounted, during the final count unless the count was incorrect. ST 1 added that at the time of Patient 2's surgery, the operating room did not use clear bags when bagging the sponges. When asked how a surgical sponge could have been retained in Patient 2, ST 1 responded, "Maybe four sponges got packaged as five, I think that's what happened, so the count would still be correct even if a sponge was missing."</p> <p>During an interview on 11/17/09 at 10 a.m., RN 5</p> | E 271  |   |  |

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| E 271   | <p>Continued From page 4</p> <p>stated she was the scrub nurse for part of Patient 2's surgery. She stated that the system of bagging sponges in groups of five during the procedure was "not good." She said that because the bagged sponges are not recounted during the final count, "You are trusting the person before you that there are five sponges in each bag."</p> <p>The facility's Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated the following:<br/>"Surgical counts will be performed utilizing the following guidelines. The use of a standardized systematic method of accounting for instruments, sponges, needles and specific small items used during a surgical procedure will promote patient safety by helping to prevent retained foreign bodies.</p> <p><b>B. Sponge Counts</b><br/>11. The scrub person shall open soiled sponges when possible before discarding. Discard soiled sponges into kick buckets with impervious liners.<br/>15. Once counted, the sponges are confined in an impervious wrapper.<br/>16. As part of the ongoing count process and during the closure counts, the total number of bagged sponges must be reconciled with the total number documented on the count board/sheet."</p> <p>The policy was ambiguous in that it did not specify that the bags had to be opened and the sponges contained in them needed to be recounted during the final sponge count</p> <p>The facility failed to develop and implement a surgical count policy and procedure which specified that bags of sponges counted during</p> | E 271  |   |  |

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| E 271 | Continued From page 5<br><br>the course of the surgery be opened and recounted during the final count. This resulted in a surgical sponge having been left in Patient 2, who had to undergo a second surgery to remove it. This failure is a deficiency that has 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. | E 271 |  |  |
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DALY CITY



California Department of Public Health

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**E 000** The following represent the findings of the California Department of Public Health during an investigation of Entity Reported Event #CAO0191275 regarding retained foreign object during surgery. The investigation of the reported event was substantiated.

The inspection was limited to the specific reported event investigated, and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

Andrea Kubovcik, R.N., Health Facilities Evaluator Nurse  
Mary Coulton, R.N., Health facilities Evaluator Nurse

Health and Safety Code Section 1280.1(c):

For purposes of this section, "immediate jeopardy" means a situation in which the licensee's non-compliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

**E 000** **Please Note:**  
The following constitutes California Pacific Medical Center (CPMC) – Pacific Campus Hospital's credible evidence of correction of all of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form CMS- 2567 dated 11/17/09. Preparation and/or execution of this credible evidence submission does not constitute admission or agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies.

The Statement of Deficiencies form is dated 11/17/09, however the hospital records indicate the survey was completed on 11/18/09 by Andrea Kubovicik, RN and Alice Morrissey, RN.

**(X5) COMPLETION DATE**

**E 264** T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures.

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

This Statute is not met as evidenced by:

**E 264** E 264, E 269, E 271

**Corrective Action:**

Failure to comply with the established Surgical Count policy has been addressed with the staff involved in this event.

**(X5) COMPLETION DATE**  
**6/09**

Licensing and certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Alice Morrissey* TITLE *Director, Risk Management* (6) DATE *02/15/10*

California Department of Public Health

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| E 269              | Continued From page 1  | E 269         | E 264, E 269, E 271 cont.   |                      |
| E 269              | T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures.<br><br>(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, a circumstances require, patient advocacy.<br><br>This Statute is not met as evidenced by:   | E 269         | The Surgical Services Policy # 27.2.1.54, "Counts, Surgical" has been revised to state:<br>"General Rules:<br>2. The count process requires <u>vigilance and continual readiness to account for required items included in a surgical count.</u> Every effort should be made throughout the procedure to be ready to perform a count at any time.<br>3. OR staff will initiate the chain of command when faced with resistance by any member of the surgical team to comply with the surgical count policy.   | 12/18/09             |
| E 271              | T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.<br><br>(d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.<br><br>This Statute is not met as evidenced by:<br>Based on interview and record review, hospital failed to implement its Surgical Counts policy and procedure when RN 1/CVC (cardiovascular charge nurse) added a retractor and blades to the surgical field without counting them, and failed to document the addition of the retractor and blades on the instrument count sheet. The hospital failed to orient staff to instruments being used in surgery and failed to implement its Vendors and Sales Representatives policy and procedure when a retractor and blades were brought to the facility the day of surgery instead of 16 to 24 hours prior to the surgery. This resulted in a | E 271         | The "Counts, Surgical" policy was revised to include standardization of count boards and count sheets as well as the process for documenting onto the boards and sheets.<br><br>There is also a record to document the count for extra instrument sets, i.e. instruments brought in by a vendor or surgeon.<br><br>In addition, "Surgical Services Handoff Guidelines" were implemented to improve critical communication elements in the OR, i.e. sponges, sharps, medications, specimens. Recommended Relief Rules were also established in an effort to reduce the number of relief breaks that may occur during a case. |                      |

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| E 271 | <p>Continued From page 2</p> <p>retractor blade having been left in Patient 1 who had to undergo a second surgical procedure to remove the retained foreign object.</p> <p><b>Findings:</b></p> <p>1. Patient 1 was admitted to the hospital on 4/14/09 for mitral valve repair and was discharged on 4/18/09. In June 2009, the patient was experiencing chest pain and was seen by her cardiologist in her home state. A subsequent chest x-ray and ultrasound determined the presence of a a metal plate in her chest area. Patient 1 was readmitted to the facility on 6/22/09 and on 6/23/09 had surgery to remove a retained retractor blade.</p> <p>On 11/16/09 at 10:50 a.m., Patient 1's intraoperative record dated 4/14/09 was reviewed, and indicated that the initial, closing and final instrument counts were documented as correct.</p> <p>There was an intraoperative report dated 6/23/09 which listed the surgical procedure as "Removal Retained Foreign Object."</p> <p>Patient 1's operative note dated 6/23/09 noted a pre and post operative diagnosis of retained foreign object. The surgeon documented that he had repaired Patient 1's mitral valve a few months ago and, "That part of the operation was successful. It required some additional retractors, however, that were brought in from the outside and these were not properly accounted for at the end of the operation and she ended up with a retractor blade lined posteriorly in her thorax that we did not recognize during her stay in the hospital. Therefore she was brought back to have it be removed."</p> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>CPMC Administrative Policy 2.98, "Universal Protocol" states:<br/>J. "Time Out" before starting the Procedure:</p> <ol style="list-style-type: none"> <li>"Time Out" must be conducted in the location where the procedure will be done and must be conducted prior to starting the procedure.</li> <li>Members of the care team are <b>expected to speak up immediately and stop the process</b> if they notice any discrepancy or believe any step in the safety check process is missed or incomplete.</li> </ol> <p>K. Sign Out:</p> <ol style="list-style-type: none"> <li>Prior to leaving the procedure area, the RN verbally confirms with the team... <ul style="list-style-type: none"> <li>Instruments, sponge and needle counts are correct</li> <li>Equipment problems to be addressed</li> </ul> </li> </ol> <p>Staff education for the "Universal Protocol" was provided during Surgical Services education meetings.</p> <p>Surgical Services Policy 27.3.0.11, "Vendors and Sales Representatives; Special Instruments/Equipment/Supplies Guidelines in the Surgical Services Department" has been revised to state:</p> | Current as of 11/19/09 |
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| E 271   | <p>Continued From page 3</p> <p>On 11/16/09 at 3:25 p.m., RN 2 was interviewed. She stated she was the scrub nurse for Patient 1's first surgery on 4/14/09. She said she was unfamiliar with the approach being used by the surgeon and that she made RN 1/CVC aware of this prior to the procedure. RN 2 said "(name of circulating nurse) and I had never done that type of case, the approach was different, RN 1/CVC was there to guide us." She stated that Surgeon 1 works very quickly. She said, "I've never worked with anyone who goes that fast." RN 2 stated the retractor and blades were brought into the operating room after the initial count had been done and after Patient 1's chest had been opened. She stated "It was the middle of the case." She said "I'd never seen these instruments or used them before." She said that Surgeon 1 wanted the retractor and blades immediately. The retractor vendor was in the operating room to answer any questions the surgeon may have had about the product. When asked if the retractor and blades were counted, she stated "I eyeballed it, but myself and the circulator didn't get time to count. I felt pressured and I didn't get time to count." She added "It was a hectic environment, the noise level was very high."</p> <p>RN 1/CVC was interviewed on 11/16/09 at 3:45 p.m. She stated she was the charge nurse of cardiovascular services and what happened was "an unfortunate event." She said that Patient 1's procedure was "entirely different to what he (Surgeon 1) usually does." She stated that a vendors representative brought the retractor and blades to the facility the morning of Patient 1's surgery, that she (RN 1) flash sterilized the instruments, brought them into the operating room and put them on the instrument table. When asked if the retractor and blades were counted, she responded "I guess that was not</p> | E 271  | <p>E 264, E 269, E 271 cont.</p> <p>3. a. New products, instrument systems, implants or equipment requests are approved through the following methods as appropriate: Value Analysis Committee, New Technology Committee, and/or the department chair/designee.</p> <p>b. <u>The operating room manager/designee will ensure that the items requested are approved.</u></p> <p>c. Approved new products and evaluations of products will be communicated through a bulletin from the Value Analysis Committee.</p> <p>d. <u>The confirmation of approved vendor instrument systems/equipment, will be communicated to the staff by utilizing the Vendor Audit Tool which will follow the instruments/equipment throughout the process.</u> The tracking tool will start at the receiving unit and end when the procedure is completed.</p> <p>e. Manager/designee and Materials Management Staff will establish a plan for contacting the vendor. The designated person will make arrangement for timely delivery of the equipment/implants required for the procedure.</p> <p>f. Manager/Supervisor/Service Leader or designee will arrange for staff education with the vendor prior to using new or unfamiliar instruments or equipment.</p> <p>D. Sterile Processing</p> <p>4. Pre-procedure sets will arrive ideally 8 to 24 hours prior to the start of a scheduled elective procedure.</p> <p>a. Instruments/implant sets must be inspected, cleaned, decontaminated, and sterilized by CPMC staff prior to patient use.</p> <p>b. Electrical equipment must be checked by Biomedical Engineering before use on any CPMC patient.</p> |

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| E 271 | <p>Continued From page 4</p> <p>done. I'm sure I counted the pieces but I can't remember specifically but that's my usual practice." When asked if she documented counting the instruments, she said "I didn't write it down."</p> <p>RN 1/CVC was asked when the retractor and blades were brought into the operating room. She stated "I brought it into the operating room after the procedure started. ( Name of RN 2) was right up there, maybe she didn't have a chance to come away from the table to count." RN 1/CVC said "(Name of RN 2) was unfamiliar with the instruments, she was on the other side of the table, she probably couldn't even see when he (Surgeon 1) took out the retractor." RN 1/CVC added" I assumed that everyone knew what to do with the retractor."</p> <p>When asked how the retractor blade was left in Patient 1, RN 1/CVC responded" He (Surgeon 1) must have just unscrewed it and left it fall into the wound. I can't believe he did that." She stated that when the surgery was finished, the retractor and blades were sent downstairs to the SPD (sterile processing department) for sterilizing. She said when the vendor picked up the instruments, he noticed that a blade was missing but he never notified the facility.</p> <p>RN 3 was interviewed on 11/17/09 at 10:30 a.m. She stated she was assigned to be the circulating nurse for Patient 1's procedure on 4/14/09. She said she was not familiar with the approach being used by Surgeon 1 so she notified her senior nurse (RN 1/CVC). She stated that RN 1/CVC was the primary circulating nurse for the procedure as she (RN 3) was going between two operating rooms. RN 3 stated she did the closing and final count with RN 2 and the retractor and blades were not listed on the count sheets. She</p> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>5. b. <u>An inventory list will be completed for instrument sets used on procedures where an instrument count is required. If the vendor is unable to provide this, the department receiving the set (OR or SPD) will complete an inventory /count list.</u></p> <p>9. Inventory lists are affixed to or included with instrument sets used on procedures where an instrument count is required.</p> <p>F. Operating Room:</p> <p>6. The circulating RN will:</p> <ul style="list-style-type: none"> <li>▪ Confirm that the product, instrument, or implants have been approved for use by CPMC</li> <li>▪ Confirm prior to the start of the procedure that the loaner instruments have been processed at CPMC,</li> <li>▪ <u>Confirm that a count sheet is included if the procedure requires an instrument count by policy.</u></li> <li>▪ <u>Confirm that the staff have received education.</u></li> </ul> <p>Surgical Services staff has been informed of the changes to the policy and are aware of their responsibilities.</p> <p><b>Monitoring Process:</b><br/>The Surgical Services staff is completing concurrent monitoring of the count process including compliance to general rules, initial count, handoff process and closing counts. Monitoring results will be reported to the Surgery and Operating Room Committee and the hospital Quality Improvement Committee.</p> | 12/18/09            |
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| E 271 | <p>Continued From page 5</p> <p>said" I never saw that retractor that day."</p> <p>The facility's Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated the following:<br/>Policy:<br/>Surgical counts will be performed utilizing the following guidelines. The use of a standardized systematic method of accounting for instruments, sponges, needles and specific small items used during a surgical procedure will promote patient safety by helping to prevent retained foreign bodies.</p> <p>A. General Rules.</p> <ol style="list-style-type: none"> <li>1. It is the responsibility of all members of the surgical team to maintain an optimal Operating Room environment to allow focused performance of operative tasks. Distractions and interruptions should be kept to a minimum during the count.</li> <li>2. Counts are performed following the guidelines for the category of the items counted.</li> <li>4. Counts are to be performed by two people, the circulating Registered Nurse (RN), and a scrub person. The circulating RN is responsible for conducting the counts and must be a participant of every count.</li> <li>5, The items are counted audibly, and concurrently viewed by the scrub person and circulating RN.</li> <li>12. Sponge types, free needles, atraumatic needles, sharps, and miscellaneous items are recorded separately on the standardized preformatted whiteboard. A preformatted work sheet mirroring the whiteboard is used when a whiteboard is not accessible. Instruments are recorded on standardized count sheets.</li> <li>13. A running total of needles, sharps, and miscellaneous items are placed on the boards,</li> </ol> | E 271 | <p>E 264, E 269, E 271 cont.</p> <p>A monitoring audit tool for vendors, with associated indicators, has been developed.</p> <p>The monitoring is conducted by surgical services staff concurrently on all vendor cases. The audit data is reported quarterly to Surgical and Operating Room Committee and to the Quality Improvement Committee.</p> <p>All vendor products that arrive less than 8 hours prior to surgery, regardless of reason, will be tracked and reviewed for system issues and common factors and will be included in the report.</p> <p>The Surgical Services Count and Vendor policies and monitoring tools are attached for your reference.</p> <p><b>Responsible Persons:</b></p> <p>Senior Director, Surgical Services and Director, Outcomes Management</p> | Current and ongoing |
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| E 271   | <p>Continued From page 6</p> <p>worksheets, and instrument count sheets will be done as items are added. The method of documenting additions and totals is standardized.</p> <p>20. When counts are performed: Instruments</p> <p>b. As new counted items are added to the field.</p> <p>D. Instrument Counts.</p> <p>1. Instrument counts are performed on all procedures involving, or reasonably anticipated to involve, the opening of a major body cavity such as:</p> <p>d. the pleural/thoracic cavity.</p> <p>3. Initial instrument count is performed following the order on the standardized count sheet.</p> <p>4. Use this standardized count sheet to document instruments added during the procedure.</p> <p>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.</p> <p>According to 2008 AORN Perioperative Standards and Recommended Practices, pg. 293,</p> <p>"Retained objects are considered a preventable occurrence, and careful counting and documentation can significantly reduce, if not eliminate, these incidents."</p> <p>Recommended Practices for Sponge, Sharp, and</p> | E 271  |   |  |

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| E 271 | <p>Continued From page 7</p> <p>Instrument Counts.<br/>Recommendation 111 (pg. 296).<br/>Instruments should be counted for all procedures in which the likelihood exists that an instrument could be retained.</p> <p>2. Instruments should be counted audibly and viewed concurrently by two individuals, one of whom should be a registered nurse circulator. Concurrent verification of counts by two individuals assists in ensuring accurate counts.</p> <p>6. When additional instruments are added to the field, they should be counted when added and recorded as part of the count documentation.</p> <p>The facility failed to implement its Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure when RN 1/CVC added a retractor and blades to the surgical field and failed to initiate an instrument count. RN 1/CVC also failed to document the addition of the retractor and blades on the instrument count sheet.</p> <p>The Director of Perioperative Services was interviewed on 11/17/09 at 2:30 p.m. and said "the vendor policy was not followed." She stated that Surgeon 1 had contacted the vendor to bring in the retractor and blades for Patient 1's surgery. The vendor brought in the instruments the morning of Patient 1's surgery and they were flash sterilized.</p> <p>The facility's Vendors and Sales Representatives: Guidelines in the Surgical Services Department policy and procedure was reviewed and revealed the following:<br/>D. Sterile Processing Departments<br/>4. Pre-Procedure:</p> | E 271 |  |  |
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Sets must arrive at least 16 to 24 hours prior to the start of a scheduled elective procedure. (Instrument sets cannot be wrapped, processed and sterilized in less than three hours from receipt of product).

7. The SPD (sterile processing department) staff will inspect all trays and process them in a washer/decontaminator or hand wash them if required.

8. SPD staff will wrap and sterilize the trays and place them onto a separate cart/area to be sent to the O.R. on the evening before or the morning of the procedure.

The 2008 AORN Recommended Practices for Sterilization in the Perioperative Practice Setting, pg.578 & pg.579 indicates the following:  
Recommendation IV

Use of flash sterilization should be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner.

Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process.

According to 2008 AORN Perioperative Standards and Recommended Practices, p.181, AORN Guidance Statement: The Role of the Health Care Industry Representative in the Perioperative Setting, "Perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment before their use in a surgical procedure. This instruction may be provided by a health care industry representative and may take place in a formal inservice program or as a

E 271 E 271 cont.

**Corrective Action:**

CPMC Surgical Services Policy and Procedure 27.3.0.8 "Flash Sterilization in the Operating Room" defines flash sterilization "as the sterilization of unwrapped items with the use of saturated steam under pressure in a gravity displacement or pre-vacuum sterilizer. Saturated steam under pressure should be used to sterilize heat and moisture-stable items". The policy and procedure references the AORN 2008 Standards of Practice.

The Procedure specifies:

4. Specialty instruments or devices are sterilized according to the manufacturer's recommendations/instructions.
9. Prior to removing the item from the autoclave, the person removing the item is responsible for examining the graph/digital autoclave printer tape to ensure that the correct time, temperature, and pressure have been met.
10. Upon removing the item from the sterilizer, and again prior to placing the item on the sterile field, examine the chemical indicator for changes.

**Both the scrub and circulating staff (or other staff opening the autoclave) are responsible for examining the indicators for change, indicating that sterilization parameters have been met.**

Complete as of 11/19/09

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| E 271 | <p>Continued From page 9</p> <p>one-on-one instruction. The facility should maintain evidence of documented competencies for perioperative team members, especially when introducing new procedures, techniques, technology, and equipment.</p> <p>The facility failed to implement its Vendors and Sales Representatives: Guidelines in the Surgical Services Department policy and procedure when the instruments for Patient 1's surgery were brought to the facility the morning of the procedure instead of at least 16 to 24 hours prior to the start of the procedure. This resulted in the instruments being flash sterilized and RN 2 and RN 3 being unfamiliar with the retractor and blades being used during Patient 1's surgery. RN 2 and RN 3 were also unfamiliar with the surgical approach being used by Surgeon 1 during Patient 1's surgery.</p> <p>This failure is a deficiency that has 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.</p> | E 271 | <p>E 271 cont.</p> <p><b>Monitoring Results:</b></p> <p>For every load sterilized, the staff record the patient information, type of case, and items sterilized. This information is reviewed along with the autoclave records.</p> <p>The data is summarized in a Quality Monitoring Report and submitted quarterly to the CPMC Infection Control Committee.</p> <p>A copy of the Flash Sterilization Policy is attached for reference and review.</p> <p><b>Responsible Person:</b></p> <p>Senior Director Surgical Services<br/>Manager, Infection Control</p> <p style="text-align: center;"><b>CALIFORNIA DEPARTMENT<br/>OF PUBLIC HEALTH<br/>APR 29 2010<br/>L&amp;C DIVISION<br/>DALY CITY</b></p> | Current and ongoing |
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