

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>CA220000019</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>C</b> <b>12/26/2008</b>
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NAME OF PROVIDER OR SUPPLIER  <b>SAN FRANCISCO GENERAL HOSPITAL</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1001 POTRERO AVENUE SAN FRANCISCO, CA 94110</b>
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E 000 Initial Comments

The following represent the findings of the California Department of Public Health during a complaint/adverse event visit: Entity Reported Event # CA00172409 regarding retention of foreign object - Substantiated.

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

Representing the Department of Public health:

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.

(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which

E 000

E 264

E 269

**E264 T22 DIV 5 ART3-70213 (a)**

Revised OR Policy #8/Sponge and Sharp Count Policy to add following statements to clarify and strengthen the sponge and sharp count procedure:

\*use of the 4.8 Raytec sponges not advised for abdominal surgery cases due to the high risk of retention

\*use of "pause" in OR suite activity by all surgical team members to perform a final sweep/examination of the surgical wound to ensure absence of retained object

Approved by OR Committee  
January 13, 2009

Licensing and Certification Division

*[Signature]*  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

*Chief Executive Officer* 9/25/09

(X6) DATE

STATE FORM

6899

1TV D11

State of California  
CDPH-L&C

SEP 25 2009

Daly City Dist. Office

*[Handwritten signature]*  
9/29/09

If continuation sheet 1 of 4

California Department of Public Health

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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	stating that sponges intentionally placed as packing will be documented in the intra-operative record. Upon return to the operating room, a radiologic assessment will be completed before final wound closure to rule out retained foreign body (see Attachment 2).	
E 269	T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures.  (b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which	E 269		

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E 269	T22 DIV5 CH1 ART3-70213(b) Nursing Service Policies and Procedures.  (b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which	E 269	<b>E269 T22 Div 5 CH1 ART3-70213 (b)</b>  Upon notification by Risk Management of the incident, the covering OR Nurse Manager conducted a phone interview	December 15, 2009

**State of California  
CDPH - L&C**

SFP 25 2009

**Daly City Dist. Office**

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E 269	Continued From page 1  includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.  This Statute is not met as evidenced by:	E 269	with RN 1 (circulator) and met with RN2 (scrub) to review <b><u>OR Policy #8/Sponge and Sharp Count Policy</u></b> and to discuss the incident and their role as patient advocates to ensure that count was correct ( <b>see Attachments 3, 4, 5</b> )  The covering OR Nurse Manager reviewed the incident and <b><u>OR Policy #8/Sponge and Sharp Count Policy</u></b> with the OR staff in a staff meeting ( <b>see Attachment 6</b> ).	December 17, 2008
E 271	T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.  (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.  This Statute is not met as evidenced by: Based on interview and record review, the hospital operating room registered nurses failed to implement the written Sponge, Sharp and Instrument Count Policy which resulted in a retained 4X8 gauze sponge in Patient 1's abdomen. The sponge was not detected until it had tunneled through her abdominal wall into her vagina.  Findings:  On 12/23/08, Patient 1's clinical record was reviewed with the hospital Risk Manager. The patient had been diagnosed with a complex pelvic tumor consistent with cancer. The results of a preoperative colonoscopy (colon exam with a lighted scope) on 9/5/08 indicated that she also had colon cancer.	E 271	RN 1 resigned during the incident investigation ( <b>see attachment 7</b> ).  The OR Nurse Manager reassigned RN 2 to the dayshift for closer monitoring of practice ( <b>see Attachment 8</b> ).  RN 2's sponge and sharp count practice was supervised by the OR Nurse Preceptor for five (5) operative cases to monitor her compliance with <b><u>OR Policy #8/Sponge &amp; Sharp Count</u></b> ( <b>see Attachment 9</b> ).  The Director of Perioperative Nursing Services reported both RN 1 and RN 2 to the Board of Registered Nursing following completion of the incident investigation ( <b>see Attachments 10, 11</b> ).	December 31, 2008  January 5, 2009  Initiated January 5, 2009 & completed January 20, 2009  February 6, 2009

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E 269	Continued From page 1  includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.  This Statute is not met as evidenced by:	E 269	RN 2 was given a 30 working day suspension for inattention to duty and failure to follow policy following completion of the incident investigation (see Attachment 12).	Initiated March 4, 2009 & completed April 3, 2009.
E 271	T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.  (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.  This Statute is not met as evidenced by: Based on interview and record review, the hospital operating room registered nurses failed to implement the written Sponge, Sharp and Instrument Count Policy which resulted in a retained 4X8 gauze sponge in Patient 1's abdomen. The sponge was not detected until it had tunneled through her abdominal wall into her vagina.  Findings:  On 12/23/08, Patient 1's clinical record was reviewed with the hospital Risk Manager. The patient had been diagnosed with a complex pelvic tumor consistent with cancer. The results of a preoperative colonoscopy (colon exam with a lighted scope) on 9/5/08 indicated that she also had colon cancer.	E 271	A Root Cause Analysis meeting was conducted to review the incident and potential corrective actions to be taken were identified including but not limited to policy revision and employee practice audits.  Revised <u>OR Policy #8/Sponge and Sharp Count Policy</u> to add following statements to clarify and strengthen the sponge and sharp count procedure:  *use of the 4.8 Raytec sponges not advised for abdominal surgery cases due to the high risk of retention  *use of "pause" in OR suite activity by all surgical team members to perform a final sweep/examination of the surgical wound to ensure absence of retained object  *definition of "high risk" cases and need for radiologic exam to ensure that all objects are accounted for regardless of the final count	January 5, 2009  Approved by OR Committee January 13, 2009

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E 269	Continued From page 1  includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.  This Statute is not met as evidenced by:	E 269	*documentation if counted sponges are used as postoperative packing  *clarification that the term "xray" refers to both xray and fluoroscopic exam  *statement that during the final count process, <u>any</u> member of the surgical team may request a recount or radiologic exam if they suspect any unintended retained foreign object (see Attachment 1).  The OR Nurse Manager conducted a formal unit-based <b><u>Adverse Event Review</u></b> with the OR staff including a review of revised <b><u>OR Policy #8/Sponge and Sharp Count Policy</u></b> (see Attachment 13).	
E 271	T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.  (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.  This Statute is not met as evidenced by: Based on interview and record review, the hospital operating room registered nurses failed to implement the written Sponge, Sharp and Instrument Count Policy which resulted in a retained 4X8 gauze sponge in Patient 1's abdomen. The sponge was not detected until it had tunneled through her abdominal wall into her vagina.  Findings:  On 12/23/08, Patient 1's clinical record was reviewed with the hospital Risk Manager. The patient had been diagnosed with a complex pelvic tumor consistent with cancer. The results of a preoperative colonoscopy (colon exam with a lighted scope) on 9/5/08 indicated that she also had colon cancer.	E 271	At this meeting, the OR Nurse Manager emphasized the advocacy role of all OR staff and the responsibility they have to advocate for patients to ensure patient safety; he reviewed responsibility of all OR staff to use the chain of command to report violations of any policy/practice that endanger patient safety.  The OR Nurse Manager conducted individual reviews of the packet of materials presented at the <b><u>Adverse Event Review</u></b> staff meeting with those OR staff not present at the January staff meeting (see Attachment 12).	Initiated January 14, 2009 & completed January 30, 2009  January 30, 2009

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E 271	T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.  (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.  This Statute is not met as evidenced by: Based on interview and record review, the hospital operating room registered nurses failed to implement the written Sponge, Sharp and Instrument Count Policy which resulted in a retained 4X8 gauze sponge in Patient 1's abdomen. The sponge was not detected until it had tunneled through her abdominal wall into her vagina.  Findings:  On 12/23/08, Patient 1's clinical record was reviewed with the hospital Risk Manager. The patient had been diagnosed with a complex pelvic tumor consistent with cancer. The results of a preoperative colonoscopy (colon exam with a lighted scope) on 9/5/08 indicated that she also had colon cancer.	E 271	The OR Nurse Manager conducted audits of the sponge and sharp count practice of all OR RN and OR Tech staff to ensure compliance with the revised policy (see Attachments 13, 14).	Quarter 1 & Quarter 2 2009

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E 271	<p>Continued From page 2</p> <p>On 9/8/08, Patient 1 underwent an exploratory laparotomy (surgical exploration of abdomen), total abdominal hysterectomy and bilateral salpingo-oophorectomy (removal of uterus, fallopian tubes and ovaries, debulking surgery (surgical reduction of tumor size) and low anterior resection (small bowel resection) followed by a left hemicolectomy (colon resection). The patient experienced massive bleeding because of a blood coagulation disorder during the eight hour surgery (8.25 hrs.), requiring multiple transfusions of blood products. In addition, there were nine O.R. staff either scrubbed (sterile) or circulating (unsterile) during this procedure.</p> <p>On 12/12/08, the patient was seen in the Gyn/Oncology clinic complaining of a foul smelling vaginal discharge. The Outpatient Progress Record on 12/12/08 indicated the following: "Spec-(specimen) foul smelling Raytec (4X8 inch gauze sponge with embedded radiopaque strip) sponge removed from vagina, some adherence to tissue above vagina, small bleeding from cavity, edges of vagina clear...Likely retained sponge at time of second laparotomy, eroded through vagina." The hospital pathology notified the risk manager on 12/15/08 about the foreign body identified on gross examination (without a microscope) as a 4X8 Raytec sponge.</p> <p>During an interview on 12/23/08 at 1:30 p.m., R.N.1, who was the final scrub (sterile nurse) on the case, told the surveyor that when she relieved RN 3 at about 7 p.m., "There were no 4X8's on the table, they were already bagged (counted in groups of 5 or 10 and placed into plastic bags)." At that time, R.N.4 was still circulating in the room (unsterile nurse). At about 9:30 p.m. R.N.2</p>	E 271	<p>*statement that during the final count process, <u>any</u> member of the surgical team may request a recount or radiologic exam if they suspect any unintended retained foreign object (see Attachment 1).</p> <p>An addendum was added to <u>OR Policy #8/Sponge and Sharp Count Policy</u> stating that sponges intentionally placed as packing will be documented in the intra-operative record. Upon return to the operating room, a radiologic assessment will be completed before final wound closure to rule out retained foreign body (see Attachment 2 )</p> <p><b>Monitoring:</b> The OR Nurse Manager will continue to review OR RN and OR Tech staff sponge and sharp count competencies annually.</p> <p><b>Responsible Person:</b> OR Nurse Manager Director, Perioperative Nursing Services</p> <p style="text-align: right;"><b>State of California CDPH-L&amp;C</b> SEP 25 2009 <b>Daly City Dist. Office</b></p>	<p>Approved by OR Committee February 10, 2009</p> <p>Ongoing</p>
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E 271	<p>Continued From page 3</p> <p>relieved R.N.4 as circulator. R.N.2 told the surveyor, "I only counted instruments, R.N.4 told me all the sponge counts were correct when I relieved her." R.N.1 told the surveyor that she and R.N. 2 had "done a final count and it was correct."</p> <p>A 12/23/08 review of the hospital Sponge, Sharp, and Instrument Policy with a revision date of 05/08 noted the following procedure regarding final counts:</p> <p>"Final counts are performed together by the scrub person and circulating nurse: a. From the surgical site and the immediate surrounding area, to the Mayo stand, and back table, to the designated disposal area, to the bagged sponges."</p> <p>When R.N.1 and R.N.2 were asked if they had counted the bagged sponges, they looked at one another and initially did not respond. R.N.2 repeated that R.N.4 had told him that all the sponges had been accounted for. Neither nurse affirmed that the bagged sponges had also been counted, as outlined in the hospital policy.</p> <p>The facility's failure to ensure that R.N.1 and R.N.2 performed the final sponge count in accordance with the facility policy and procedure, 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		