The following reflects the findings of the California Department of Public Health during the investigation of an Entity Reported Incident.

Representing the California Department of Public Health: Health Facilities Evaluator Nurse (HFEN) 1872.

The inspection was limited to the specific complaints/entity reported incidents investigated and does not represent the findings of a full inspection of the facility.

Incident/Complaint Number CA00152420

T22 DIV5 CH1 ART9-70223(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.

Based on clinical record review, policy and procedure review, and staff interview, the hospital failed to ensure that the Surgical Service nursing staff implemented the policy and procedure titled, "Sponge and Sharps Count," resulting in a surgical lap pad (sponge) being retained in Patient 1's abdominal cavity

Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. This Plan of Correction is prepared and/or executed solely because it is required by Health and Safety Code Section 1280.

Action Plan for 70223(b)(2)

Sutter Lakeside Hospital has in place Medical Staff Committees with assigned responsibilities in the development, maintenance, and implementation of written policies and procedures.

A Root Cause Analysis was conducted on 6/3/08. As a result, the following five action plans were developed and implemented.

1) All surgery staff will review and demonstrate understanding of Policy and Procedure #PC 35-044, entitled "Sharps and Sponge Count" (the "Sharps and Sponge Count Policy").
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following surgery. Patient 1 had to undergo another surgical procedure to remove the lap sponge, placing the patient at increased risk for complications due to the additional surgery and anesthesia.

THE FOLLOWING EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), WHICH PUT THE HEALTH AND SAFETY OF SURGICAL PATIENTS AT RISK. WHEN NURSING STAFF FAILED TO IMPLEMENT THE HOSPITAL'S WRITTEN POLICY AND PROCEDURE TITLED, "SPONGE AND SHARP COUNT," AND IDENTIFY PRIOR TO SURGICAL CLOSURE THAT A LAP SPONGE WAS RETAINED IN THE PATIENT'S ABDOMEN. THIS FAILURE PLACED THE PATIENT AT RISK FOR INFECTION AND COMPLICATIONS FROM A SECOND SURGICAL PROCEDURE TO REMOVE THE LAP SPONGE.

Findings:

Review of Patient 1's clinical record on 6/13/08, indicated that Patient 1 was admitted to the hospital on 5/21/08 for a paraesophageal hernia repair and graft surgery on 5/21/08 at 7:30 a.m.

Review of the Intraoperative Record dated 5/21/08, indicated that sponge counts were performed prior to the surgical procedure and prior to closing, and that both counts were correct. Review of the Report of Operation dated 5/21/08 revealed, "...Sponges placed to

Implementation: On 5/30/08, 6/13/08, and 7/11/08, all surgery staff reviewed the Sharps and Sponge Count Policy and demonstrated correct sharps and sponge counting technique to the RN Director of Surgery and/or Surgery Clinical Coordinator.

2) Association Operating Room Nurse (AORN) guidelines will be reviewed by the RN Director of Surgery to ensure the Sharps and Sponge Count Policy represents the current AORN standards.

Implementation: In 6/08, the RN Director of Surgery reviewed the Sharps and Sponge Count Policy and determined that it met the current AORN guidelines.

3) The RN Director of Surgery will ensure preceptors for new employees are competent in the sponge count process by return demonstration.

Implementation: In June, 2008, the RN Director of Surgery assessed all preceptors' competency in the sponge count process by observing the preceptors return demonstration.
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facilitate exposure were also removed. Instruments and sponges were counted and confirmed times two ...

Review of the Imaging Report, dated 5/28/08, revealed, "Curvilinear density in the left upper abdomen concerning for an intra-abdominal foreign body, possibly a surgical sponge. Correlate clinically ...The findings of this study was discussed with [Patient 1's surgeon] on 5/28/08 at 12 p.m."

Review of the Report of Operation, dated 5/28/08, revealed, "...There was a retained mini laparotomy sponge which was removed without difficulty."

Review of the hospital's policy and procedure titled, "Sponge and Sharps Count", PC 35-044, review date 1/2008, demonstrated that the count protocol requires that sponges are counted audibly and viewed concurrently as they are separated and counted by two individuals, one of whom should be an RN, prior to the procedure, prior to wound closure, and at skin closure or end of procedure.

The Surgical Tech stated in an interview on 6/13/08 at 1:55 p.m., that he performed a sponge count with a Registered Nurse prior to the procedure. The count was five large sponges, five small lap sponges, 10 Raytec sponges. The Surgical Tech stated that two sponges were inserted into the abdomen by the surgeon and two were removed. When

4) The RN Director of Surgery or designee will review the Intra-operative Record form for appropriateness and in-service surgery staff on the form and documentation process.

Implementation: The Surgery Department's Unit Base Council revised the Intra-operative Record form to improve clarity and ease of use. The Risk and Quality Manager and the RN Director of Surgery conducted a documentation in-service for surgery staff on 9/4/08.

5) The RN Director of Surgery will review and assess available sponge count assist devices for the Main OR suites.

Implementation: In 9/08, the Surgery Department purchased sponge count bags to support accuracy in large intra-abdominal cases. The Sharps and Sponge Count Policy was revised to include the addition of the sponge count bags to our procedure. The surgery department staff were inserviced on the use of the sponge count bags and on the revised policy by the RN Clinical Coordinator.

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 discloseable 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 discloseable 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.
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asked, the Surgical Tech stated that he was not in the room the entire time of the procedure, but had informally performed a count with his relief before and after his break. The surgical tech stated that he did not know how they had missed the retained sponge.

Review of the Authorization For and Consent to Surgery or Special Diagnostic or Therapeutic Procedures, dated 5/28/08, demonstrated that Patient 1 was notified of a need to remove a foreign body.

Patient 1 stated, in an interview on 8/14/08 at 11:36 a.m., that the surgeon informed her prior to the second surgery that a sponge had probably been left in her abdomen.

The Director of Surgical Services, stated during an interview on 10/9/08, that the facility had performed a Root Cause Analysis and the Surgical Services Committee would be informed of the report during the October meeting. The Director of Surgical Services stated that competency validation performed with the surgical nursing staff is done on initial orientation and that the annual validations are not operating room specific with the exception of conscious sedation. Competency is reviewed by reported errors and that the charge nurses and managers observe tasks performed by staff.

The hospital failed to implement the sponge count policy, resulting in the requirement for

The Root Cause Analysis report was reviewed by the Surgery Subcommittee on 11/28/08. The Subcommittee recommended that the Sharps and Sponge Count Policy be revised to require a sponge count during any rest breaks, lunch breaks, and shift change. The surgery staff were in-serviced on the revised Policy by RN Director of Surgery in December, 2008.

Monitoring Process:

The Clinical Coordinator and RN Director of Surgery will conduct observational audits for compliance with the Sharps and Sponge Count Policy for one quarter, from April 2009 through June 2009.

The RN Director of Surgery, Clinical Coordinator, or designee will audit 20 charts a month for one quarter in the Main OR and all surgical charts in the Family Birth Center beginning April 2009 through June 2009 for compliance with the Policy.

There have been no reported incidents of retained sponges or foreign objects in the Surgery Department since 5/21/08.
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subsequent operative removal of a retained sponge in Patient 1.

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