CALIFORNIA HEALTH AND HUMAN SERVICES .NCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	051317	A. BUILDING _____ B. WING _____	11/18/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
St Helena Hospital - Clearlake	15630 18TH AVE. - HWY. 53, CLEARLAKE, CA 95422 LAKE COUNTY

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	The following reflects the findings of the California Department of Public Health during an ENTITY REPORTED INCIDENT visit. ERI NUMBER: CA00168577 Inspection was limited to the specific ENTITY REPORTED INCIDENT investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: Surveyor 20307, Medical Consultant 1 (MC1). THE DEPARTMENT SUBSTANTIATED A VIOLATION OF THE REGULATIONS. 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 interview, document review, and medical record review, the facility failed to implement its sponge, needle, and instrument count policy for Patient 1's surgical procedure. The result was an adverse event involving retention of a foreign object		**Corrective Action:** Extensive review of policy 7420.20.006 *Sponge, Needle and Instrument Counts*, was performed by the Surgery Department Director on November 3rd, 2008. The policy demonstrated current and complete process and inclusive of the required surgery counts including disposable instrumentation with removable parts in the count process. After this review, intensive education for surgery staff of the policy pertaining to sponge, needle and instrument count was completed November 3rd, 2008. The education on the policy and required surgery counts was held during staff meeting held by Surgery Department Director. All surgery staff attended and completed a review of the entire policy and demonstrated understanding of required compliance with the policy. After the surgery staff completed educational review of the *Sponge, Needle and Instrument Counts* policy, the Surgery Director with the Director of Nurses and our facility surgeons adopted the World Health Organization surgical safety checklist to reduce risk of surgical errors in the future. The WHO surgical safety checklist has many safety improvement features; two of the key components of the WHO checklist are; timeouts completed with the surgeon prior to the surgery and verification of complete surgery counts at the end of the procedure. The counts at the end of the procedure are verbally confirmed and completed between the nurse and the	Completed 11/30/2008

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tate-2567 6/4/09 Judi Bolden, QM notified that POC accepted. TB

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	Continued From page 1 in a patient after surgery. THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), WHICH PUT THE HEALTH AND SAFETY OF PATIENT 1, AS WELL AS OTHER PATIENTS UNDERGOING SURGICAL PROCEDURES, AT RISK WHEN THE SURGERY DEPARTMENT STAFF FAILED TO IMPLEMENT THE HOSPITAL'S WRITTEN POLICIES AND PROCEDURES FOR SPONGE, NEEDLE, AND INSTRUMENT COUNTS, RESULTING IN THE RETENTION OF A FOREIGN OBJECT IN A PATIENT AFTER SURGERY. Findings: In interview on 11/18/08 at 9:30 am, Administrative Staff A explained that on 10/28/08, Physician A performed a sigmoid colectomy (surgical removal of the lower colon) on Patient 1. During the procedure, a disposable (one use) stapling instrument was used to join the two cut ends of colon where the diseased portion had been removed. The instrument consisted of two parts. One was placed above the upper cut edge of the remaining colon, and the other was inserted through the anus and placed at the lower cut edge. The two parts were then joined and locked, incorporating the upper and lower tissue borders. The instrument was then fired, causing surgical staples to bring the edges together in a permanent circumferential anastomosis. The stapling instrument was then removed. It was not noticed that the upper part of the instrument was not connected to the lower part at the time the instrument was removed from the		**Continued** surgeon and documented on the check list at the end of each procedure/surgery. The safety checklist was reviewed and approved for use by the surgeons at the medical staff surgery committee meeting November 18th, 2008. The safety check list was implemented November 24th, 2008 after all surgery staff completed education on the use of the form, the requirements and expectations. The Surgery Department Director began monitoring use and compliance November 24th. The surgery Department Director has reported compliance to Surgery Medical staff meeting monthly since December. In addition to monitoring the complete WHO checklists, the Surgery Department Director randomly monitored staff and surgeon compliance to the WHO safety checklist process by observing the intra-operative process. A brief inservice on the use of the stapler was held during the surgery staff meetings in November by the Surgery Department Director. During the Surgery Medical Staff meeting November 18, 2008, a review of appropriate handling and use of the stapler was performed with the surgeons. **Responsible oversight:** Director of Nurses with Surgery Department Director. **Compliance Monitoring:** Under the Nursing Director leadership, the surgical safety checklist based on the WHO surgery safety guidelines was created. The	Ongoing Thru August 2009 and

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	Continued From page 2 patient's rectum. No staff member noticed that the instrument was not complete. Administrative Staff A stated that several days later, Patient 1 had a bowel movement and noticed a clanking noise in the commode. A metallic structure found in the commode was determined to be the upper part of the stapling apparatus. The structure was subsequently forwarded to the manufacturer for evaluation of a possible defect. The stapler had been disposed of at the end of the case and was not available for evaluation. Staff did not notice that the stapler was not complete at the time of its disposal. Review of the medical record on 11/18/08 at 0930 demonstrated that the initial sponge count and sharp count on 10/28/08 were recorded as correct. The initial instrument count box was not checked. The second and third sponge, sharp, and instrument count boxes were not checked. A late hand-written entry dated 11/6/08 stated that the second sponge and sharp counts had been correct, and the first instrument count had been correct. There was no additional information regarding a third sponge and sharp count or a second or third instrument count. Review of the medical record on 11/18/08 at 0930 demonstrated that the operation on 10/28/08 proceeded without complication, and the integrity of the stapled anastomosis of the two portions of colon was verified. On 11/1/08, Patient 1 received a rectal suppository at 1:15 pm to aid in evacuation. The record included documentation that Patient 1		**Continued** use of the checklist in surgery department began on November 24. Nurses complete the checklist on every surgical procedure and send the completed form to the Surgery Department Director. The compliance rate is calculated by the department director and reported to the quality department and to surgery medical staff committee monthly. Rates of compliance with WHO safety checklist for December thru February was 94% with February reaching 100% compliance. Monitoring of WHO checklist will continue thru August 2009 maintaining 100% compliance and randomly monitor compliance after August. In addition to monitoring the WHO checklist compliance, the Surgery Director randomly monitored compliance with sponge and needle counts by direct observation and staff interviews during December 2008 and January, February 2009. Compliance in February is reported at 100%. Corrected Page 2, 5/8/09	Randomly Afterwards Maintaining 100% Compliance Completed 2/28/2009

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	Continued From page 3 had a bowel movement at 2:30 pm, and the nurses note stated that Patient 1 informed staff that it "felt like something heavy fell out of his butt." There was no complaint of increased pain. The staff found a metal object in the commode. Abdominal x-ray at 6:51 pm on 11/1/08 demonstrated no retained intra-abdominal structure. On 11/5/08, in an addendum to the discharge summary, Physician A stated that he was informed that Patient 1 had passed the retained upper portion of the stapling device without difficulty and that he had discussed the occurrence with Patient 1, telling him that no damage would ensue. In interview on 11/18/08 at 9:45 am, Physician A stated that he had performed at least 50 procedures with the stapler and had never left a piece in before. He stated that the stapler is designed so that the upper piece, which he called the anvil, is locked to the stapler for the cutting and stapling and remains attached to the stapler as it is removed. Physician A conjectured possible equipment failure. He stated that he was focused on insuring the completeness of the closure and did not inspect the stapler, which was handed off to the circulating nurse, bypassing the scrub technician because it was contaminated. Physician A stated that he then turned to the abdominal incision to close the abdominal wall. On 11/18/08 at 10:15 am, review of hospital policy 7420.02.006; Sponge, Needle, and Instrument Counts, approved by the governing board on 1/29/04, demonstrated the following: "Instruments			

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	Continued From page 4 that are broken or disassembled during the procedure must be accounted for in their entirety." In addition, the policy states that "sharps and instruments must be counted audibly and viewed concurrently by the scrub person and the circulating nurse together." The policy also states that instrument counts are to be performed before the procedure and again before wound closure begins. The facility failed to implement surgical policies and procedures regarding the accounting of all equipment used in surgery, when a piece of a surgical stapler was left in Patient 1's intestine. The facility's noncompliance with this regulation is likely to cause serious injury or death.			

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