CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050006	A. BUILDING _____ B. WING _____	08/12/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JOSEPH HOSPITAL	2700 DOLBEER ST., EUREKA, CA 95501 HUMBOLDT COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00277671 - Substantiated Representing the Department of Public Health: Surveyor ID # 16932, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Penalty number: #110008611 E347 T22 DIV5 CH1 ART3 - 70223 (b) (2) Surgical Services 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.		Compliant Number CA00277671 Penalty number: #110008611 E347 T22 DIV5 CH1 ART3–70223(b)(2) **Temporary and Permanent Corrective Action:** 1. The hospital policy, Surgical Counts: Sponges, Sharps and Instruments was reviewed, 7/27/11, and found to be adequate in addressing the need to count additional items that are added to the surgical field. Such items are to be counted at the time they enter the surgical field and recorded on the count board to keep the count current and accurate. 2. Interview of surgical staff on 7/28/11 to determine the department practice for counting visceral retractors when added to the surgical field. 3. "Fish" retractors added to the white board in the operating room and uniformity of practice reviewed at the department morning meeting on 7/28/11. 4. Review of Count Policy during staff meeting on 8/1/11 regarding instruments, such as fish, and the requirement for counting at time of entry into the surgical field. 5. Interdisciplinary meeting on 8/10/11 with Chief of Surgery, Medical Director of Radiology, Surgical Services Director, Quality Director, and Chief Medical Officer to review and integrate the Surgical Count policies of Surgical Services and Diagnostic Imaging.	8/12/11 8/12/11 8/12/11 8/12/11 8/12/11

Event ID:ZXNK11 10/7/2011 11:21:12AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Ann Warner RN Director, Quality + Risk Programs 10/25/11

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POC accepted 11/4/11 Juanita Gleich HFEN

Ann Warner notified

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	Continued From page 1 Based on observation, staff interview, and document review, the hospital failed to ensure that the operating room (OR) teams followed policy and procedures for accounting for all items placed inside the patients during surgical procedures. This failure resulted in Patient 1 having a retained foreign object (a Visceral Retractor) that caused prolonged post-operative pain and subjected Patient 1 to the additional risks of a second surgery to remove the retained object. THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WITHIN THE MEANING OF HEALTH AND SAFETY CODE SECTION 1280.1 IN THAT IT CAUSED, OR WAS LIKELY TO CAUSE SERIOUS INJURY OR DEATH TO THE PATIENT, WHEN MEDICAL AND NURSING STAFF FAILED TO IDENTIFY THAT A FOREIGN OBJECT (A VISCERAL RETRACTOR) HAD BEEN RETAINED IN A PATIENT AFTER SURGERY. THIS VIOLATION PLACED THE PATIENT AT INCREASED RISK FOR COMPLICATIONS AND DEATH FROM THE RETAINED VISCERAL RETRACTOR AND SECOND SURGERY REQUIRED RETRIEVING THE FOREIGN BODY. Findings: On [redacted]/11 the hospital reported to the California Department of Public Health that Patient 1 had a retained object following an abdominal surgical procedure. Record review on 8/10/11 indicated that Patient 1		6. Revised Surgical Count Policy reviewed at Surgical Services Staff meetings. 7. Review of staff competencies, 7/2011, for surgical services nursing and surgical tech annual competencies to include direct observation of staff performance of each step in the surgical count process (opening, closing and final counts). 8. Interdisciplinary consulting team of surgeon, OR nurse, and Risk Manager competed a three day assessment of perioperative services. Interviews will hospital staff, surgeons, and anesthesiologists as well as one day of direct observation in the Surgical Services Department. 9. Ongoing Perioperative Nursing and Surgical Tech education in November 2011 using AORN materials for education (AORN: *Preventing Retained Surgical Items*). 10. Implementation November 2011 of new quality monitoring indicator for auditing of count process by direct observation.	9/12/11 9/16/11 8/12/11 10/13/11 ongoing ongoing

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	Continued From page 2 was admitted to the facility on [redacted]/11 for a surgical repair of an abdominal hernia. Review of the Surgical Record dated [redacted]/11, indicated that Surgeon A was notified that both the first and final count of the instruments was correct prior to wound closure. Review of a computerized topography (CT) scan report dated [redacted]/11 indicated that Patient 1 had a, "linear metallic flat object..." in the abdomen near the surgical scar. Patient 1 was readmitted to the hospital on [redacted]/11 for surgery to remove the foreign object. The Operation Record dated [redacted]/11, indicated that the patient had abdominal surgery to remove a, "bluish foreign object, which appeared to be a visceral retractor. The large sized visceral retractor was removed. The string that was attached to it was intact as was the ring." During interview on 8/10/11 at 2 p.m., Surgeon A stated that he performed a hernia repair on Patient 1 (on [redacted]/2011) that required the use of a mesh to reinforce the abdominal wall. Surgeon A stated that during the procedure he used a device called a, "viscera retainer" to hold the bowels out of the way as he sewed the mesh into place. Concurrent observation of a "FISH" revealed that it was labeled as a "Visceral Retractor" and a "FISH" on the packaging. The "FISH" was a baby blue colored, flat, vinyl object shaped like a flounder, measuring 10 inches in length and 6.5 inches at the widest section. At one end of the "FISH" was a 9 inch string that was looped through a blue vinyl ring that was approximately 2 inches in diameter.		**Description of Monitoring Process:** 1 Direct observation of the surgical count process for each aspect of the count process, opening, close and final counts. 30 cases to have direct observation of one or more aspects of the count process monthly. Monitoring for correctness and uniformity of process. Reported within the department and to the Medical Staff Quality Committee. **Person Responsible for Correction:** 1. Director of Surgical Services 2. Director of Quality and Risk Programs 3. Chief Medical Officer 4. Chief Nursing Officer	ongoing

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	Continued From page 3 Surgeon A stated that the "FISH" was moved around in the abdomen as the surgery progressed and that the string and loop were supposed to be kept outside of the incisional area. Just prior to completely sewing the abdomen closed, the surgeon would remove the "FISH" by using the loop and string to pull it out through a small opening. The opening was then sewn shut. Surgeon A stated that after Patient 1 went home, her post-operative pain level did not decrease as expected. After monitoring the patient's pain for two months, Surgeon A stated that he ordered a CT scan of the abdomen which identified that there was a foreign object in the patient. (On [redacted]/2011) When he viewed the CT scan he realized that the "FISH" was still in the patient. Surgeon A performed a second surgery (on [redacted]/2011) on Patient 1 to remove the "FISH" from her abdomen. Surgeon A stated that most likely the string and loop had been pulled into the abdomen when the "FISH" was moved from one area to another and that no one on the surgical team noticed. When the mesh was sewn in place the blue color of the "FISH" was not visible beneath it. Without the loop and string to remind the team that the "FISH" was in the abdomen, it was forgotten. Surgeon A stated that usually all items used during surgery that were placed inside the wound were counted before the wound was closed to ensure that nothing was left inside the patient. Not until the incident did he realize that the "FISH" was not			

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	Continued From page 4 included in the count. During an interview on 8/11/11 at 9:30 p.m., OR Staff B stated that the procedure was to count all instruments, sutures, needles, knives, sponges etc., and prior to beginning of the surgery. Anything brought into the room after the surgery started was written on a board on the wall called the "white board." As the surgeon got close to completing the surgery, the team counted everything listed. Everything was counted again before the final closure. Staff B stated that the "FISH" was not used for every hernia repair and that it was usually brought into the room late in the surgery. Staff B stated that because the "FISH" came in so late it was not usually written on the white board. It was, therefore, not included in the counting of instruments. During an interview on 8/10/11 at 3:45 p.m., Administrative Staff C stated that after the incident she interviewed all of the OR staff and determined that only one of the staff routinely wrote the, "FISH" on the white board. That staff member was not part of the surgical team on the day the FISH was left in the abdomen of Patient 1. Review of hospital policy titled, "Surgical Counts: Sponges, Sharps and Instruments revised March 2010, indicated that it was hospital policy, "to count instruments on all procedures in which the likelihood exists that an instrument could be retained." The facility's failure to implement written policies			

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	Continued From page 5 and procedures to prevent the retention of a visceral retractor during a surgical procedure in violation of Section 70223(b) (2) of Title 22 of the California Code of Regulations was a deficiency that caused, or was 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. This facility failed to prevent the deficiency(ies) as described above that 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(c).			

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