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
	050510	A. BUILDING _____ B. WING _____	03/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPITAL - SAN RAFAEL	99 MONTECILLO ROAD, SAN RAFAEL, CA 94903 MARIN COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit. Complaint Intake Number: CA00244476 - Substantiated Representing the Department of Public Health: Surveyor ID # 25952, 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: #110008500 E 347 T22 DIV5 CH1 ART3 - 70223(b) (2) Surgical Services General Requirement (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.			

Event ID: RFUY11 8/26/2011 11:27:58AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: COO-CNO | (X6) DATE: 9/14/2011

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 disclosable 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 disclosable 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.

POC accepted 9/19/11 10:45am w/m Peggy Ross RN Acting Regulat + Licensing Coordinator - HFEN # 2123

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	Continued From page 1 Based on observation, interview and record review, the facility failed to properly develop, maintain, and implement a surgical count policy that ensured all items on the surgical field were counted. This violation caused or is likely to cause serious injury or death to a patient. On [redacted]10, surgery was performed and a piece of gauze was retained in the patient which resulted in an infection of the surgical wound. Findings: During an interview on 10/5/10 at 2:25 p.m., Administrative Staff A stated as she reviewed Patient 1's medical record, that Patient 1 had laparoscopic surgery (minimally invasive procedure with use of lighted scope and video camera) on [redacted]2010 for gallbladder and kidney surgery. Administrative Staff A stated that on [redacted]10, during a post-operative appointment, Physician B found that Patient 1's epigastric (upper abdominal) incision area was slightly firm with shiny, waxy skin which appeared to be a superficial stitch infection. Review of Patient 1's physician progress notes, dated [redacted]10, on 10/5/10 at 2:55 p.m., indicated that the epigastric incision was opened by the Physician B and copious purulent material came out of the wound. Physician B probed the wound and documented that a "retained FB"(foreign body) of 3-4 inches of Iodoform (Iodine- antiseptic impregnated) gauze packing was removed from the wound and sent to pathology for gross examination. On 10/5/10 at 3 p.m., during a review of supplies		**Immediate Action:** The surgical team, including all licensed staff, technicians, and surgeons involved in the surgery, reviewed the newly revised policy "Counts: Sponge, Sharp, Miscellaneous Small Items/Devices and Instruments" (09/03/2010). The policy had recently been broadened in scope to include all items with a potential of becoming 'retained foreign objects' in the count process, and was in process of implementation at the time of the discovery of the retained foreign object. The surgical team concluded that the newly revised policy addressed the count process successfully and, if it had been in place at the time of the patient's surgery, this incident would not have occurred. The revised policy will be going for final review and approval by the Medical Executive Committee. **Responsibility:** PeriOperative Services Director Director Risk Management Assistant Physician-in-Chief Surgical Services	9/29/10

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	Continued From page 2 used for the surgical procedure listed on the "Surgical Encounter" electronic record dated [redacted]10, Administrative Staff C stated that there was no Iodoform gauze on the list of supplies charged, and Administrative Staff C also stated that it would not have been on their count sheet if the item was used on the surface not inside the body. During an interview on 10/5/10 at 3:40 p.m., Licensed Staff D stated that the surgery performed on [redacted]2010 required three set-ups (3 separate sterile instrument and supply table set-ups) and the patient was positioned and draped three different times with several doctors doing surgery. Licensed Staff D stated that she did not remember opening gauze for any of the procedures, and the skin was clear and without infection before they started. During an interview on 10/5/10 on 4:05 p.m., Technician E stated that he assisted the physician by holding the camera during the procedure and did not remember that there was any "Iodoform" gauze that was used. Technician E stated that during past surgeries, he had seen Xeroform (petrolatum based gauze dressing) that was used around the large surgical port at the base of the skin to help keep air from escaping, when the abdomen was inflated to allow scope visualization of the abdominal cavity. Technician E stated the gauze that is used around the trocars (surgical instrumentation used for laparoscopic procedures) had not been a part of the count before; however, stated that any item that was used on the surgical procedure should have been counted.		**Immediate Action Continued:** All staff from the operative area, were made aware of the incident and trained regarding the recent policy revision expectations that, as a rule, non-radiopaque dressing materials should be withheld from the field until the wound is closed or the case is completed. If required in a case, these items are to be called out, noted on the white board and included in the count process. Training was provided to the majority of the operative staff via huddles at change of shift. The remaining operative staff received face-to-face inservices regarding the incident and recently approved changes to the "Counts: Sponge, Sharp, Miscellaneous Small Items/Devices and Instruments" (09/03/2010) policy. **Responsibility:** PeriOperative Services Director Manager PeriOperative Services	09/24/10 - 10/22/10

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During an interview on 10/5/10 at 4:20 p.m., Administrative Staff F stated that they just had revised their surgical count policy on 9/3/10 and they were still in-servicing staff and physicians on the new policy. Administrative Staff F stated that not all the staff had read the new policy yet.

On 10/5/10 at 4:25 p.m., during an interview, Licensed Staff G stated that the old count policy was not as detailed, in that it indicated to count sponges, needles and sharps and when to count, but it was not specific about other items that should be counted.

During an interview on 10/6/10 at 10:50 a.m., Licensed Staff H stated that although she did not remember any Xeroform or Iodoform type gauze that was used on this surgical procedure, Licensed Staff H stated that it had not been the practice to count gauze that was put around the trocar in the past.

Review of the pathology report on 10/6/10 at 11 a.m., with a result date of [redacted]10, indicated that a 17 x 2-cm (centimeter) gauze like material was identified. The report indicated that a foreign body was removed from the epigastric incision site.

During an interview and observation, on 10/6/10 at 11:05 a.m., Licensed Staff G stated that the pathologist's description was reflective of the size of "Xeroform" gauze which was used in the operating room and presented a sterile package of 1 inch by 8 inch (2.5 cm x 20.3 cm) "Xeroform" petrolatum gauze dressing.

Systemic Action:
The policy, "Counts: Sponge, Sharp, Miscellaneous Small Items/Devices and Instruments" (09/03/2010), was revised to decrease the potential for 'retained foreign objects'. — 09/03/10

Responsibility:
PeriOperative Services Director
Manager PeriOperative Services

The annual performance evaluation and competency validation process for licensed staff and technicians has been expanded by the Perioperative Services to include the policy "Counts: Sponge, Sharp, Miscellaneous Small Items/Devices and Instruments" (09/03/2010). This includes focus on staff understanding that: — ~~11/30/11~~ 9/30/11 (CB telephone verification of change - Reg'l RCS accreditation + Lic CCS director 9/19/11 on 10:48am.)

- Only x-ray detectable materials are used in surgical wounds or in the body
- Non-radiopaque gauze dressing materials are withheld from the field until the wound is closed or the case is completed
- an item that is tucked or packed into the wound, is verbally announced and written on the count board; as items are removed from the wound, they are crossed off of the "tucked or packed" items count.
- The RN circulator and the scrub person include misc items in the count process

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	Continued From page 4 During a telephone interview, on 10/15/10 at 2:30 p.m., Physician I stated that he did not remember if gauze was put around trocars to prevent leaks during the surgery, which sometimes was the practice. Physician I stated that he didn't think the gauze was put in the wound afterward in the physician's office. Physician I stated that it had to have been put in during the surgery. During a telephone interview on 10/15/10 at 3:33 p.m., Physician B stated that he did not remember any Iodoform or Xeroform gauze used that could have been on the surgical field, and did not use the gauze for wound packing for the surgery. Physician B stated that about 3 months later, during an office visit, he noticed that Patient 1's abdominal incision area was shiny, and the skin looked like it was going to break down. Physician B stated that he thought it was a reaction to the stitches and opened the incision and drained out a fair amount of pus, probed the wound and pulled out gauze which he stated was a foreign body. During a telephone interview on 10/18/10 at 11 a.m., Patient 1 stated that after the fifth week after surgery, she felt a pain in her abdomen and during an office visit, Physician B thought an incision on her abdomen was infected by a stitch underneath the skin and Patient 1 stated that the physician opened up the incision and pulled a long strip of gauze out of her abdominal area. Patient 1 stated that the doctor said someone left it in and did not know how it happened.		**Systemic Action Continued:** This competency evaluation was implemented for initial competency for new staff in November 2010. Inclusion of this competency for existing staff was initiated in 2011 and will be part of the annual process in 2012. **Responsibility:** Adult Services Director Manager PeriOperative Services Ongoing focus on the count process is occurring at monthly Operating Room Staff meetings. **Responsibility:** Interim Director Perioperative Services Manager PeriOperative Services	Ongoing

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	Continued From page 6 During a telephone interview on 10/21/10 at 1.55 p.m., Physician J stated that she saw Patient 1 about three weeks after the surgery and stated at that time that there were no problems with her abdominal incisions. Physician J stated that she did not place any gauze in her wounds and that the gauze must have been left in at the time of the surgery. On 3/22/11 at 2:10 p.m., a review of the hospital's revised surgical count policy, titled "Counts: Sponge, Sharp, Miscellaneous Small Items/Devices And Instrument" effective 9/8/10, indicated that only "x-ray" detectable materials should be used in surgical wounds or body cavities and non- radiopaque (non-x-ray detectable) gauze dressing, should be withheld from the surgical field until the wound is closed or the case is completed. The policy indicated that the purpose of the policy was to ensure that the patient was not harmed as a result of retained foreign body. On 7/7/11, review of the Association of Operating Room Nurses 2011 edition of Perioperative Standards and Recommended Practices, "Recommended Practices for Prevention of Retained Surgical Items" indicated under Recommendation 1, that retained surgical items are preventable events that can be reduced by implementing multidisciplinary system and team interventions and that establishing a system that accounts for all surgical items opened and used during a procedure constitutes a primary and proactive injury-prevention strategy. All items		**Monitoring:** Ongoing monitoring activities in the OR include: 1) Direct validation by observation that staff are following the surgical counts policy 2) White board audits that documentation of count process is accurate and complete, which included tucked and misc. items Immediate feedback to individuals is provided and monitoring results are shared at Operating Room Staff meetings. Continued monitoring of a minimum of ten random cases per month will occur. Results from monitoring activities are reviewed and actions are taken as necessary by the Surgical Safety Committee, and the Quality Council that reports to the Medical Executive Committee. Monitoring will be completed after determination by the Quality Council that a sustained acceptable threshold of performance has been reached. **Responsibility:** Interim Director Perioperative Services Manager PeriOperative Services	11/01/10 - Current 10/01/11

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	Continued From page 6 needed to be accounted for at the end of a procedure so that all team members can be sure that a surgical item is not left in the patient. Information under Recommendation 2, indicated that all soft goods used in surgical wound should be radiopaque and easily differentiated from non-radiopaque soft goods (e.g. sponges, towels). Non-radiopaque gauze dressing materials should be withheld from the field until the final count was conducted. The facility failed to develop, maintain and implement a surgical count policy that required all items used on the surgical field to be counted when a surgery was performed. This violation 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. 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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