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
	050168	A. BUILDING _____ B. WING _____	08/18/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E. VALENCIA MESA DRIVE, FULLERTON, CA 92835 ORANGE COUNTY

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	The following reflects the findings of the Department of Public Health during the investigation of COMPLAINT NO: CA00158947 Inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: [redacted], HFEN. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY T22 DIV5 ART3-70223(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. This regulation is NOT MET as evidenced by: Based on interview and record review, a non-radio opaque drape, used during surgery, was not included in the operation room count which resulted in the drape being left in the patient after surgery. Consequently, the patient required another surgery to remove the drape.		**a. Corrective Action accomplished:** **Temporary:** There was an immediate change in the process of counting equipment in the surgical suite. Any time a new item is placed on the operative table it will be accounted for on the white count board. Education to all staff and physician was accomplished within the next week following the incident. **Permanent:** Change in Count: Sponge, Sharp and Instrument policy was completed. This was taken to Surgery Quality Review committee. Nursing education and competencies were completed. Prior to closure of a case the circulating nurse asks "Is everything accounted for" prior to closing the incision. The temporary changes were kept as permanent. **b. Responsible person:** [redacted] RN Director Surgical Services **c. Monitoring:** Count Audits are ~~completed each month on 10~~	**9/15/2008**

Accepted B.K. 12/30/08

Event ID:EUCH11 12/9/2008 10:46:10AM

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

CMO/VPMA 12/10/08

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	Continued From page 1 Findings: 1. Operative counts are performed to account for items and ensure that the patient is not injured as a result of a retained foreign body. The implementation of accurate count procedures helps promote an optimal patient outcome (Association of periOperative Registered Nurses, 2004). The hospital's policy and procedure for "Count: Sponge, Sharp and Instrument" showed all items inserted into a wound and not intended to be left in the wound after closure, would be noted on the count board. On 8/13/08, review of Patient A's medical record showed, on an operative report, the patient had an abdominal hysterectomy (removal of the uterus) on 7/30/08. The surgery began at 1533 hours and ended at 1728 hours. Further review of the medical record, showed the patient had another surgery on 7/30/08. This surgery, which began at 1922 hours on 7/30/08, was for removal of a retained abdominal foreign body. On 8/18/08 at 1000 hours, RN A was interviewed. The nurse said that prior to surgery she assisted with opening the surgical equipment and supplies, which included a two and one-half foot plastic surgical drape (a drape, when used in surgery, is a piece of cloth, plastic, or paper arranged over a patient's body designed to provide a sterile field around the operative incision). The nurse then said she did the first count with Nurse B. The nurse said she did not notice the surgical drape during the		cases by staff not participating in the surgery. These audits are reported to the Surgery Quality Review committee.	

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CMO/CNO 12-11-08

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	Continued From page 2 count. According to RN A, surgical drapes are not usually counted as they are not used in the wound. RN A stated that, during the surgery, the surgeon put the drape in to hold the patient's bowel back. The RN went on to say that, during the course of the surgery, the plastic drape wasn't readily visible because it was obscured by the patient's bowel. On 8/20/08 at 1730 hours, Nurse B was interviewed. The nurse said that on 7/30/08 she prepared equipment and supplies for Patient A's surgery including the drape. She said the drape was a type usually used for eye surgeries. She said she put the plastic drape in a pitcher (used for wound irrigation) in order to moisten it, set it at the back of the table, and did not include it in the count. When asked why a drape was moistened, the nurse stated the surgeon liked it moistened before using it in the wound. When asked if the drape was usually counted, the nurse said she could not remember counting it when it was used for surgeries before. Nurse B stated Surgeon D put the drape in the patient's wound to hold back the patient's bowel during the surgery. The nurse said that she did not call out that this drape was being used at that time so that it would be added to the surgical count. She stated she should have. After the patient went to the recovery room Surgeon D called Nurse B to ask "did we remove the drape?" Nurse B stated she told the surgeon she did not remember the drape being removed.			

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	Continued From page 3 Subsequently, the patient was brought back to the operating room, the incision reopened and the drape removed. According to the Director of Surgical Services, during an interview on 8/18/08 at 0855 hours, the drape was not counted and should have been. Also, if an item not in the count was placed in the wound this should be noted by the surgical team so it could be placed on the count board. 2. In the article "Preventable Errors in the Operating Room: Retained Foreign Bodies after Surgery-Part I" in Current Problems in Surgery 2007, the recommendations are that the "use of a drape towel creates an unsafe, non-standardized practice by a surgeon. When placed in a body cavity, an unmarked towel not included in the count, may not be detected and increases the possibility of a retained foreign body." The article also went on to note the recent Veterans Affairs directive on Prevention of Retained Surgical Items which mandated "all surgical towels, sponges, laparotomy pads and similar materials that are placed in the surgical field must ... be detectable by radiograph (X-Ray)." The hospital policy and procedure for "Count: Sponge, Sharp and Instrument" showed all sponges used for a surgical procedure shall be radiopaque (detectable by X-ray). On 8/13/08, review of Patient A's medical record showed, on an operative report, the patient had an abdominal hysterectomy on 7/30/08. The surgery		**a. Corrective Action accomplished:** **Temporary:** Changes in the count process were accomplished immediately. Any time a new item is placed on the operative table it will be accounted for on the.white count board. Education to all staff and physician was accomplished within the next week following the incident. **Permanent:** Change in Count: Sponge, Sharp and Instrument policy was completed. This was taken to Surgery Quality Review committee. Nursing education and competencies were completed. Prior to closure of a case the circulating nurse asks "Is everything accounted for" prior to closing the incision. Operative equipment is not always able to be radio opaque. Many new items are plastic and cannot be found by xray. The instrument count system is the method to account for all equipment. **b. Responsible person:** [redacted], RN Director Surgical Services	**9/15/2008**

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P.D. CNO/CPMA 12-18-08

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	Continued From page 4 began at 1533 hours and ended at 1728 hours. Further review of the medical record, showed the patient had another surgery on 7/30/08. This surgery, which began at 1922 hours, was for removal of a retained abdominal foreign body. On 8/18/08 at 1000 hours, RN A was interviewed. The nurse said prior to surgery she assisted with opening the surgical equipment and supplies, which included a two and one-half foot plastic surgical drape. The nurse then said she did the first count with Nurse B. The nurse said she did not notice the surgical drape during the count. According to RN A, surgical drapes are not usually counted as they are not used in the wound. The nurse said usually lap sponges are used to hold bowel back but she believed this surgeon used this drape to hold the bowel back. The nurse said surgical drapes are not radiopaque. RN A stated that, during the surgery, the surgeon put the drape in to hold the patient's bowel back. The RN went on to say that, during the course of the surgery, the plastic drape wasn't readily visible. On 8/20/08, Nurse B was interviewed. The nurse said that she prepared equipment and supplies for Patient A's first surgery including the drape. She said the drape was a type usually used for eye surgeries. She said she put the plastic drape in a pitcher (used for wound irrigation) in order to moisten it, set it at the back of the table, and did not include it in the count. When asked if the drape was usually counted, the nurse said she could not remember counting it before. When asked if the surgeon routinely used the drape in surgery, the		**c. Monitoring:** Count Audits are completed each month on 10 cases by staff not participating in the surgery. These audits are reported to the Surgery Quality Review committee.	

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	Continued From page 5 nurse said she did not routinely work with Surgeon D but with the surgeon's partner Surgeon E. According to Nurse B, Surgeon E routinely used this drape during the surgery, wanted it moist, and Surgeon D was expected to use the drape. The nurse went on to add that Surgeon D did use the drape to hold back the patient's bowel during surgery. The nurse went on to add that during the surgery the patient's bowel obscured the drape. According to Nurse B, after surgery, the patient went to the recovery room. While the patient was in the recovery room, Surgeon D called Nurse B to ask "did we remove the drape?" Nurse B stated she told the surgeon she did not remember the drape being removed. Review of a radiology report showed an abdominal X-ray was taken on 7/30/08 at 1902 hours. The reason listed for the X-ray was for "question of a retained drape." The findings showed unusual linear opacities overlying the mid abdomen which could represent a drape within the abdomen or else wrinkled sheets covering the patient, the X-ray was not definitive to what was in the abdomen. Review of Surgical Record 0731-0508, showed the patient was taken back to the operating room. In the operating room the patient was reintubated (the airway was put back in) and the patient was placed under general anesthesia again. The patient's wound staples and sutures were removed, the surgical wound opened and explored by the surgeon. The surgeon found the drape in the patient's upper abdomen, removed it, and the			

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	Continued From page 6 wound was closed using staples and sutures. The patient was extubated and taken to recovery room According to Webb MD, insertion or removal of airways may cause respiratory problems such as; coughing, gagging, or muscle spasms in the voice box. Insertion of airways can also cause an increase in blood pressure (hypertension), and increased heart rate (tachycardia). Other complications may include damage to teeth or lips, swelling in the larynx, sore throat, and hoarseness caused by injury or irritation of the larynx. According to e-medicine, complications from general anesthesia may include death, heart attack, and stroke. Less serious complications may include nausea or vomiting, sore throat, headache, shivering, and delayed return to normal mental functioning. The retention of a foreign body for Patient A resulted in a second surgery, reinsertion of an airway, and another exposure to general anesthesia. The violation(s) has caused or is likely to cause, serious injury or death to the patient(s).			

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CMS/UPIRN 12-18-08

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