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
	050503	A. BUILDING _____ B. WING _____	04/30/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MEMORIAL HOSPITAL - ENCINITAS	354 SANTA FE DRIVE, ENCINITAS, CA 92024 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit: Complaint Intake Number: CA00225644 - Substantiated Representing the Department of Public Health: [redacted], 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 Health and Safety Code Section 1279. 1 (c), The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report was made. The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code 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.		RECEIVED CA DEPT OF PUBLIC HEALTH AUG 11 2010 LICENSING & CERTIFICATION SAN DIEGO NORTH DISTRICT OFFICE	

Event ID BHUS11 7/21/2010 10:36:31AM

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

Gina Jackson - Admin Director Quality 8/5/10

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	Continued From page 1 Title 22 70223 (b) (2) A Committee of the medical staff shall be assigned responsibility for: 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 interviews and record review, the facility failed to ensure that OR (operating room) personnel recorded the use of a malleable retractor, put into Patient A's abdomen during surgery, on the OR whiteboard as required per policy. The facility also failed to ensure that OR personnel correctly counted surgical instruments at the completion of abdominal surgery for Patient A. As a result, a malleable (flexible) retractor remained in Patient A's abdomen and the patient required a second surgical procedure to remove it. Findings: Patient A, a 66-year-old female, was admitted to the facility on 4/16/10, per the Inpatient Face Sheet. Patient A signed a, "Consent To Surgery" form on 4/16/10. According to the consent, the facility scheduled Patient A for a hemorrhoidectomy (removal of hemorrhoids) with a possible open colectomy (removal of some of the bowel); possible anterior perineal resection (removal of the lower part		DPH Response – Complaint # 00225644 70223(b)(2) a) The patient was taken from the Recovery Room to the Operating Room within two hours to remove the retractor. The patient was discharged home on post op day five with no untoward sequelae. b) Review (recreated scenario) of surgical instrument count process to identify opportunities for improvement. Person Responsible: Manager of Surgical Services, Admin Director of Quality c) Observations of surgical procedures to validate current instrument count process. Person Responsible: Manager of Education and Staff Development	4/16/10 4/17/10 5/11/10

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	Continued From page 2 of the colon for cancer); and a colostomy (the creation of an opening from the colon to the surface of the body to serve as an anus). According to the Intraoperative Clinical Documentation, Patient A's surgery began at 6.01 P.M. on 4/16/10 and concluded at 9:53 P.M., **4** hours and 42 minutes later. Documentation on the same report shows that the initial count of sponges, Sharps and small items to be used in the hemorrhoidectomy was performed by CN 1 (Circulating Nurse 1) and ST 1 (Scrub Technician 1). CN 1 and ST 2 performed the initial count for sponges, Sharps, small items and instruments for the abdominal surgery. At the conclusion of the surgery, CN 1 and ST 1 did the two closing counts for the hemorrhoidectomy. CN 2 and ST 1 did the three closing counts for the abdominal surgery. According to the documentation on the Intraoperative Report, "counts complete surgeon notified." Patient A arrived in the Post Anesthesia Care Unit (PACU) at 10:10 P.M., per the PACU/POST-OP documentation. According to the notes, Patient A was unresponsive and asleep at that time. At 11.30 P.M., an x-ray taken of Patient, A's abdomen showed that one of the retractors used during the first surgical procedure remained in the patient's abdomen. The surgeon discussed the findings with the patient's family and decided to return the patient to surgery to remove the retractor. According to the second operative report, the patient tolerated the procedure well and returned to		d) Revised the *Facility Wide Counts: Sponge, Needle, Instrument, And Small Items* Policy to add : ▪ Surgeon will announce audibly when any sponge, towel, instrument or other item is placed into a cavity and the circulating nurse or designee shall note such item on the count board (prior to this event, instruments placed in surgical cavity were not written on the white board. As part of policy change, instruments are now included on white board information). ▪ Final instrument count should not be considered complete until instruments used in closing are removed from the wound and returned to the scrub person, kept separate from the other instruments and counted with the circulating nurse ▪ All towels placed in a body cavity must be x-ray detectable ▪ Radiopaque towels opened onto the sterile field must be counted Person Responsible: Manager of Surgical Services e) Reinforced education with appropriate staff regarding the Counts policy and revisions made to the policy at Staff Meetings, Stand-ups, and /or email and educational attestations Persons Responsible: Manager of Surgical Services, Manager of Birth Pavilion	5/28/10 5/14 - 6/2/10

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	Continued From page 3 the PACU in stable condition. The OR Supervisor talked about the incident during an interview on 4/30/10 at 10:00 A.M. The OR Supervisor described the malleable retractor or ribbon retractor, as a flexible metal instrument, approximately 12 inches long and 1 inch wide. The OR Supervisor stated that the surgeon used the retractor during the surgery to hold the patient's intestines out of the way in order to visualize the operative sile The OR Supervisor said that the surgeon bent the retractor into a horseshoe shape and placed it in Patient A's abdomen in the shape of a letter "U". The surgeon placed the curve of the "U" towards the patient's head and the two ends of the "U" pointed towards the patient's feet. The OR Supervisor added that when the surgeon placed the retractor in the patient's body, the item should have been added to the instrument count on the whiteboard in the OR by CN 2. The OR Supervisor explained that any item used inside a patient's body cavity should be recorded on the whiteboard during the procedure so that staff responsible for counting at the end of the surgery could ensure that nothing remained inside the patient. ST 1 discussed the incident during an interview on 5/26/10 at 10:40 A.M. ST 1 said that she recalled Patient A's surgery and confirmed that she was not the ST who performed the initial count but joined the team just as the surgeon was opening Patient A's abdominal cavity. ST 1 said that there were several retractors on the surgical field and three people using the instruments, a surgeon, a PA (physician's assistant) and a student PA. ST 1 said		f) Physicians educated regarding policy changes. Persons Responsible: Director of Medical Staff Services and Manager of Surgical Services g) Conducted initial audits to evaluate staff's adherence to the revisions in the policy. Will continue monthly for six months. Person Responsible: Manager of Surgical Services, Administrative Director of Quality	5/17/10-5/28/10 5/28/10 and repeated 7/13/10

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	Continued From page 4 that the surgeon asked for the malleable retractor, which she handed to him. According to ST 1, the surgeon did not say that he was using the retractor in the patient's abdominal cavity, so ST 1 did not tell CN 2 to add the instrument to the whiteboard. ST 1 added that sometimes a surgeon would say when he/she left instruments in the patient's body but sometimes he/she did not. ST 1 said that she could not clearly visualize the operative field because of the patient's positioning for surgery and did not see the surgeon place the retractor inside the patient. ST 1 said that at the end of the surgery, she counted with CN 2. ST 1 said that both she and CN 2 identified a retractor that they saw on the surgical field as the malleable retractor, but since realized that it must have been another retractor. ST 1 said that there were 4 different types of retractors used for Patient A's surgery. ST 1 could not explain how both she and CN 2 failed to correctly identify the retractors for the closing count. According to ST 1, she was in the OR cleaning up after the surgery when the PA called the OR, spoke to ST 1 and questioned whether or not she saw the malleable retractor removed from Patient A's abdomen. ST 1 said that she could not recall if the retractor had been removed but told the PA that the instrument count was correct. ST 1 said she went to sterile processing, where surgical instruments were taken after surgery, and opened the packet of instruments that had been used for Patient A's abdominal procedure. ST 1 said she could only find one malleable retractor in the package instead of two. ST 1 informed the surgeon who performed the			

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	Continued From page 5 surgery and he ordered an x-ray The x-ray showed that the retractor was still inside the patient's abdomen. The surgeon discussed the findings with the patient's family who were at the PACU and they agreed to a second surgical procedure to remove the retractor. Consequently, Patient A returned to surgery and the retractor was removed. During an interview with CN 2 on 5/26/10 at 10:40 A.M., CN 2 stated that she was not present at the beginning of the surgery and did not perform the initial counts. CN 2 stated that she took over from CN 1 at about the time the surgeon opened Patient A's abdomen CN 2 said that there were no instruments listed on the whiteboard to be counted and that during the surgery, neither the surgeon nor ST 1 said that the malleable retractor was in Patient A's abdomen. CN 2 said that had she known that the retractor was used in the abdominal cavity, she would have recorded it on the whiteboard for the final count According to CN 2, at the end of the surgery, she did the count with ST 1 CN 2 said that it was her practice to read down the list of instruments. As she visualized each instrument with the scrub technician, she checked the item off from the list CN 2 said that she saw one of the two malleable retractors provided in the abdominal tray, still in the tray. CN 2 stated that both ST 1 and she looked at the operative field to identify the second retractor and both thought that a retractor they saw was the malleable retractor. CN 2 also said that the retractor that both OR personnel mistook for the malleable retractor must have been counted twice			

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	Continued From page 6 during the final instrument count, once correctly and once incorrectly for the malleable retractor. CN 2 could not explain how the mistake happened According to the Anesthesia Record, dated 4/16/10, Patient A returned to the OR for a second surgery to remove the retained retractor. Anesthesia began for the second procedure at 11:56 P.M., and ended at 12:52 A.M. The surgery itself began at 12.08 A.M. and ended at 12:30 A.M. The surveyor reviewed the facility's policy and procedure entitled, "Counts: Sponge, Needle, Instrument, and Small Items," last reviewed 8/08. According to the policy, "V. Procedures.. C. Instruments are counted on all procedures in which the likelihood exists that an instrument could be retained." The facility failed to ensure that OR personnel accounted for the use of a malleable retractor, placed in Patient A's abdomen during surgery, on the whiteboard in the OR. The policy required that the instrument be added to the count as there was a likelihood that the retractor could be retained. The facility also failed to ensure that ST 1 and CN 2 correctly identified a retractor while doing the instrument count at the conclusion of Patient A's surgery. As a result, a 12 x 1 inch flexible retractor was left in the patient's abdomen. This failure resulted in Patient A having to go back to the OR for a second surgical procedure The facility's failure to ensure that OR personnel accounted for the use of a malleable retractor is a			

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	Continued From page 7 deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health & Safety Code section 1280 1 (c) 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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