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
	050324	A. BUILDING _____ B. WING _____	08/09/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MEMORIAL HOSPITAL - LA JOLLA	9888 GENESEE AVENUE, LA JOLLA, CA 92037 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00247732 - Substantiated Representing the Department of Public Health: Surveyor ID # 22363, 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 1280.1 (c)SAN 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. Informed Adverse Event Notification 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 is made.." The CDPH verified that the facility informed the patient or the party responsible for the patient of the		The facility failed to ensure that OR Staff followed the policy and procedure, firstly by not counting or ensuring the removal of the temporary pin inside Patient A's cervical spine, and secondly by not ensuring the radiologists read the X-Rays prior to Patient A leaving the OR and communicate the findings with the surgeon per the facility policy. A. How the correction will be accomplished, both temporarily and permanently. Item # 1- not counting or ensuring the removal of the temporary pin inside Patient A's cervical spine 1. A specific section for "Temporary Items" was added to the Operating Room whiteboard used to record items placed inside the patient. 2. The Surgical Count Policy was revised to include "when an item intended for temporary use is placed in a patient, such as a spacer or pin, it will be noted on the white board and counted". 3. Also included in the policy and an expectation of staff at any time equipment is placed inside a patient is that [Counts] "are audible and concurrently visualized by both the	

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Mary M Cleland | CHIEF EXECUTIVE | AUGUST 29, 2011

Any deficiency statement ending with en 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

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	Continued From page 1 adverse event by the time the report was made. Health & Safety 1279.1 (a) HSC Section 1279 (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. . Disclosure of individually identifiable patient information shall be consistent with applicable law. 1279.1 (b) For purposes of this section "adverse event" includes any of the following: 1279.1 (b) (1) (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. 70223 (b) (2) Development, maintenance and implementation of writtan 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. 70587 (f) Adequate communication shall be maintained with referring physicians. The facility failed to follow their policy and procedures related to counts in the OR (operating room) and communication between the radiologists		scrub person and the Perioperative RN circulator". 4. Vendor trays were significantly reduced in order to ensure staff familiarity with the temporary items contained in the trays. Item # 2 - not ensuring the radiologists read the X-Rays prior to Patient A leaving the OR and communicating the findings with the surgeon per the facility policy. 1. The cause of the retained foreign body was determined to be that the pin was partially hidden behind a surgical retractor when the X-Ray was performed. This was not appreciated by the surgeon during review of the fluoroscopy study intra-operatively or in the subsequent review by the Radiologist. In order to ensure clear visuallzation of the surgical field when an X-Ray is taken, the following was added to The Surgical Count Policy "All radiopaque materials should be removed from the surgical field before the "final" X-ray is taken. This includes retractors".	

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	Continued From page 2 and the surgeon. As a result Patient A left the OR with a retained pin which necessitated a return to the OR for a second surgery to remove the unintended retained pin Findings: Patient A was admitted to the facility for spine surgery on [redacted]/10. On [redacted]/10 from 7:30 to 10:30 a.m., Patient A had a C5-T1 anterior plate and screw fixation and unilateral right sided pedicular screw and rod posterior fixation T1-T2 (stabilization of the lower cervical and upper thoracic spine through the use of surgically placed permanent hardware). During the surgery a temporary pin (measuring 2.5 cm) was used to stabilize the spine. Prior to leaving the operating room fluoroscopy (real time X-ray) of the operative site was performed. A second and third X-Ray were obtained at 5:30 p.m. and 10:00 pm following the surgery on [redacted]/10. Patient A complained of discomfort throughout the evening [redacted]/10) following surgery. According to the nursing documentation, Patient A complained of feeling something stuck in her throat at 8:35 p.m.. Something moving in her neck at 9:30 p.m., and finally difficulty breathing at 10:00 p.m. Following the 10:00 p.m. complaint of difficulty breathing the surgeon was notified and another X-Ray of the operative site was ordered and done. At 10:30 p.m., Physician X (the surgeon) went to the hospital to view Patient A's X-Rays and noted the temporary pin used during surgery had not been removed.		The Surgeon utilizes a fluoroscopy study in the OR Suite to determine proper placement and review for any potential retained foreign bodies. It was determined through the root cause analysis process that there was no additional value to having a radiologist not familiar with the equipment view the study intra-operatively therefore this was removed from the policy. 2. The policy was amended to require radiologic exam only under the following circumstances: • When two or more pleural and peritoneal cavities are entered. • The use of 50 or greater lap sponges. • Any time a patient is returned to the OR for removal of sponges intentionally left in for packing during a previous surgery or for removal of an unplanned retained item	

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	Continued From page 3 Patient A returned to surgery on [redacted]/10 at 11:00 p.m., for a second surgery to remove the temporary pin. Following the surgery Patient A developed some difficulty swallowing and hoarseness in her voice, requiring swallow and speech evaluations. Eventually Patient A recovered and was discharged home on [redacted]10. On 11/19/10 at 8:00 a.m., the surgeon (physician X) was interviewed. According to Physician X, he used a small temporary pin during surgery. He was aware it was temporary and had planned to remove it. Physician X recalled he visualized the surgical area with fluoroscopy (real time X-Ray imaging) during surgery; however, retractors (an instrument used to pull back the muscle and secure the opening while performing surgery) were left in during the fluoroscopy inspection. Physician X stated that retrospectively, the temporary pin could be seen on the print out from this fluoroscopy. According to Physician X, the pin was along the edge of a retractor and difficult to see if one was not looking specifically for it. Physician X stated a retraction instrument is used to remove the temporary pin, and recalled removing the pin, however he did not nor did the OR (operating room) staff , check the end of the instrument to assure that the pin had been removed. Physician X stated he was not called with the reading of the intra-operative or the 5:30 p.m. post-operative X-Ray which showed a linear object impinging on the airway. He was not notified until Patient A developed respiratory distress, at which time he ordered the 10:00 p.m.		3. A radiologic exam is recommended for correct counts under the following circumstances: • Surgical cases lasting 7 hours or more • When three or more permanent scrub reliefs occur • Unexpected surgical approach or change in procedure, e.g., appendectomy that converts to bowel resection. • For procedures in which accurately accounting for instruments is not achievable, (e.g., total hip, spine procedures with instrumentation, liver transplant, procedures that require instruments with numerous removable small parts, e.g., Birmingham retractor), an intra-operative • x-ray will be taken before closure to confirm the absence of foreign bodies.	

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	Continued From page 4 X-Ray, which he read himself and discovered the temporary pin had not been removed. Dr A and Dr B, the two Radiologists responsible for the X-Ray readings were interviewed on 11/19/10 at 8:30 a.m. Dr A, the radiologist who read the intra operative fluoroscopy film, explained that the X-Ray (read at 4:30 p.m.), is not read live in these spinal cases, which is why the reading was timed 4:30 p.m. (after surgery). Dr B was the radiologist who read the 5:30 p.m. film with the first recognition of the linear object. According to the radiologists they both believed the object to be part of the surgical hardware. The radiologists explained that many different types of procedures with many different types of hardware are performed at the facility. Dr B's reading of the 5:30 p.m. X-Ray was reviewed and read as follows: "...There is a 3 cm linear horizontally oriented object that appears to be attached to the superior portion of the plate with its tip located in the region of the airway..." The radiologists stated that the surgeon (Physician X) was not notified in this case, because they did not perceive the object as foreign but thought perhaps it was an unusual variant. The facility policy and procedure entitled Counts: Sponge, Needle, Instrument, and Small Items was reviewed with administrative staff on 11/4/10 and again on 11/19/10. According to the policy, "To minimize the risk of retained instruments during procedures in which accurately accounting for instruments is not achievable (eg, anterior-posterior spinal procedures), an intra-operative X-Ray will be taken before closure to confirm the absence of		B. The title or position of the person responsible for the correction. Director of Surgical Services, Donna LoCurto. C. A description of the monitoring process to prevent recurrence of the deficiency. Reports are generated from our electronic documentation system to confirm radiologic exams are completed according the criteria cited above. Exams will only be completed as ordered or in accordance with this policy. D. The date the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty days from the date of the exit conference. 1. Education regarding the changes to the whiteboard and the expectation of calling out temporary items; and the changes to the Surgical Count Policy which included both the counting of temporary items and the changes in X-Ray criteria were presented to OR Staff during the morning stand up meetings on 11/18/2011, 11/9/2010, 11/22/2010 and 11/23/2010. Any OR Staff not present during these meetings	

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	Continued From page 5 foreign bodies. This must be read by a radiologist before the patient is discharged from the OR. The surgeon will take responsibility for ensuring that tha film is read promptly by contacting the radiologist or the covering Night Hawk radiologist to confirm the results in a timely manner." The same policy under Procedures, section 4, reads as follows: "Small items are counted on all procedures in which the likelihood exists of being retained. This includes, but is not limited to, cotton balls, umbilical tapes, disposable instruments inserts, acorns, Q tips, rubber gaskets, vessel loops, safety pins, peanuts, cottonoids, ligaclip bars, vascular inserts, cautery scraper pads, suture reels, and bulldogs." According to administrative staff, temporary pins are not considered countable small items. Administrative staff stated that typically in these cases the surgeon is the one responsible to read the films since the hardware placed is most familiar to the surgeon and the radiologist is less familiar with the different types of hardware inserted by the different surgeons and different vendor sets used in the OR. The facility's failure to ensure that OR staff followed the policy and procedure, firstly by not counting or ensuring the removal of the temporary pin inside Patient A's cervical spine, and secondly by not ensuring the radiologists read the X-Rays prior to Patient A leaving the OR and communicate the findings with the surgeon per the facility policy is a deficiency that has caused, or is likely to cause,		2. were required to sign the Information in the Stand-Up Communication Book. 3. The above information was shared with the Medical Staff during the Spine Committee meeting held on 11/19/2010.	

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	Continued From page 6 serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the Health and 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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