POC accepted Susan Lotman 7/22/13

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000162	A. BUILDING: _____ B. WING _____	C 02/22/2013

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RONALD REAGAN UCLA MEDICAL CENTER	757 WESTWOOD PLAZA LOS ANGELES, CA 90095

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E 000	Initial Comments The following reflects the findings of the Department of Public Health during an entity reported incident investigation. Complaint Intake # CA00281298- Substantiated The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility, Representing the Department of Public Health: Evaluator ID# 31335, RN, HFEN 1280.1(c) Health and Safety Code Section 1280 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 likely to cause, serious injury or death to the patient.	E 000		
E 347	T22 DIV5 CH1 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 Statute is not met as evidenced by: Based on record review and interview, the facility	E 347	7/12/2013 Since this incident in 2011, our facility has taken many measures to ensure the safety of our patients. Our plans of action include: 8/1/2011 The facility introduces our yearly Failure Mode Effectiveness Analysis (FMEA) topic: Surgicount Initiative. Surgicount is a bar coding system using RFID sponge technology as an adjunct system to assist with surgical sponge count practice. The FMEA included a review of the new system as well as the development of an anagram that descriptively includes the new process mapping.	

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E 347	Continued From page 1 failed to implement its written policy and procedure on counting sponges used for Patient 1's surgical procedure which resulted in retention of a foreign object (lap sponge) in the patient's abdomen. On [redacted] 2011, Patient 1 underwent an Exploratory Laparotomy (a laparotomy is a large incision made into the abdomen, and is used to visualize and examine the structures inside of the abdominal cavity), Cholecystectomy (surgical removal of the gallbladder), and a resection of tumor mass anterior body of pancreas. A lap sponge was left in the patient's left lower abdominal which required a second surgical procedure under general anesthesia to remove a retained sponge. The facility's failure placed the patient at risk for possible additional complications [e.g. bleeding, infection, shock, adhesions, ileus (paralysis of the bowel), changes in blood pressure, heart rate or heart rhythm and allergic reaction to general anesthetic medicine]. Findings: On February 14, 2013, an unannounced visit was made to the facility to investigate an entity reported incident on a retained foreign object (lap sponge) after a surgical procedure on Patient 1. A review of the Discharge Summary for Patient 1 disclosed the patient was admitted to the facility on [redacted], 2011, and discharged on [redacted] 2011. The admitting diagnosis was hepatic flexure colon cancer. (Hepatic flexure is a bend in the colon that connects the ascending and transverse colon.) The discharge diagnoses included hepatic flexure colon cancer and retrained foreign body. According to the Operative Record dated [redacted] 2011, Patient 1 underwent an Exploratory	E 347	(Continued from page 1) OR dept safety talk Topic: Safe and Quality Care: The Importance of Communication and Culture. This OR safety talk continued until all staff involved has received the talk. Responsible Party: Director of Peri Operative Services FMEA – Surgicount Initiative 8/1/2011 FMEA subgroup meets weekly to discuss the progress of implementation of the Surgicount Initiative. This group was primarily responsible for the policy standardization and revision across the health system. This group was responsible for ensuring that staff education was provided to all targeted areas throughout the UCLA Health System. Responsible Party: Director of Peri Operative Services Notification of Medical Staff Informational letter sent out to all Medical Staff from Surgicount representative staff. Responsible Party: Director of Peri Operative Services Email Blast to all involved staff Email blast to all staff from the Director of Peri-operative services was sent. The email blast included the pilot kick off schedule, as well as education on the Surgicount system, the letter that was sent to the Medical Staff, and a recent article from the Joint Commission of the Journal on Quality and Patient Safety. Responsible Party: Director of Peri Operative Services Implementation of "Surgi-count" Staff Education/In-service was provided and reviews of the pilot kick-off schedule of the new program "Surgi-count". Responsible Party: Director of Peri Operative Serivces	8/14/2011 5/01/2012 8/8/2011 8/24/2011 9/7/2011

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E 347	Continued From page 2 Laparotomy, Cholecystectomy, and a resection of tumor mass anterior body of pancreas. The Operating Room Nursing Record for Patient 1 dated [redacted] 2011, disclosed that the preliminary count was conducted by Employee 1 and Employee 3 and it was correct. The first count and the final counts were done by Employee 2 and Employee 4, and they were correct. However; according to the Discharge Summary, on the fourth post-operative day a Gastrografin study (swallowing of contrast follow by an x-ray) was done to assess for duodenal (the first part of the small intestine) leak, which did not show any leak. Instead, the study showed the ribbon like structures in the left lower abdominal. The repeat KUB (an x-ray of the kidneys, ureter, and bladder) was completed and again it showed the same image of the object. A review of Patient 1's X-ray of the abdomen dated [redacted] 2011, indicated "one or two ribbon like densities projecting over the left abdomen are unchanged and likely lap pad markers." A review of the Operating Room Record for Patient 1 dated [redacted] 2011, disclosed Patient 1 underwent a second surgery of an exploratory laparotomy to remove a foreign body under general anesthesia. The Operating Room Record indicated a preoperative and postoperative diagnosis of retained lap sponge. During an interview on February 22, 2013 starting at 1:05 p.m., Employee 1 (Circulating Nurse) stated that there were three (3) sponge counts, the preliminary count was done before the first incision, the first count was done before the closing of the body cavity, and the final count was	E 347	(Continued from Page 2) The in-room trails begin The pilot included trialing the system in (5) rooms of the main OR.The system was trialed in five OR Suites. The trial continues daily for 12 hours at a time. The trial lasts from 9/12/2011 through 9/23/2011. Responsible Party: Director of Perioperative Services Administrative Nurse 1 meeting An update of the patient safety initiative was provided to this group. Roles and responsibilities changes targeted to this group were also discussed. Responsible Party: Director of Perioperative Services Grand Rounds presentation Surgicount education,data review,and implementation information was discussed with the group. Responsible Party: Director of Medical Staff Surgical Faculty Group presentation Surgicount education,data review,and implementation information was discussed with the group. Responsible Party: Director of Perioperative Services Policy revision The Health System Count Policy final draft submitted for leadership approval. (applies to perioperative services and labor & delivery in the UCLA Health System) Surgicount Team on site for go live ramp up and staff training. Responsible Party: Director of Perioperative Services In-service Count policy changes and overview and Surgicount training with staff. Responsible Party: Director of Perioperative Services Data Review 360 reports were reviewed by leadership and selected staff. Responsible Party: Director of Perioperative Services	9/23/2011 12/21/2011 2/15/2012 4/5/2012 7/3/2012 7/11/2012 7/12/2012

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E 347	Continued From page 3 done before closing of the skin. Employee 1 stated as sponges were added or removed from the field they were separated and put on each finger of one hand, followed by 2 staff members verifying the count of the sponges. Employee 1 also stated that he was unsure of how a sponge was missed. Employee 1 further stated Employee 2 (Circulating Nurse), Employee 3 (Scrub Nurse), and Employee 4 (Scrub Tech) verified the procedures on counting sponges. Employee 1 added that if a doctor used a sponge for packing and leaves it in the body cavity, they were to inform the nurses in the OR and that count would be included in the count. None of the employees were able to explain how a sponge was left in the patient when the documentation indicated the count was correct. A review of the facility's policy and procedure titled, "Counts, Sponges and Sharps, Misc., Instruments" dated June 2010, indicated the purpose was to provide guidelines for sponges, sharps, miscellaneous, and instrument counts during a surgical procedure to ensure patient safety. The policy indicates: (1) Mandatory counts are performed visually and audibly by the scrub person and circulating nurse. (1.1.1) The scrub person and circulating nurse must be independent practitioners in their designated role. (1.1.2) Sponges, sharps and miscellaneous items are counted at the initial count - prior to the start of the procedure, first count - prior to the closure of the body, and final count - skin closure. (1.1.2.2) Scrub person and circulating nurse count all instruments on thoracic, abdominal, retroperitoneal, and pelvic surgical procedures. The facility's failure to implement its policy and	E 347	(Continued from page 3) Implementation Health System wide Go Live with Surgicount scanning at RR & SMN Main Operating Rooms and Labor and Delivery rooms. Responsible Party: Director of Perioperative Services Morbidity & Mortality Review topic: Preventing RFOs A presentation was made to the group that discussed the FMEA, Surgicount process, Health System policy and procedure changes as a related to the implementation of Surgicount. Responsible Party: Director of Anesthesia	7/16/2012 7/23/2012

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E 347	Continued From page 4 procedure to prevent retention of a lap sponge during a surgical procedure for Patient 1 is a deficiency that has caused, or likely to cause, serious injury or death to the patient, and therefore constitutes and immediate jeopardy within the meaning Health and Safety Code Section 1280.1	E 347		