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PRINTED: 07/03/2009
FORM APPROVED

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
	CA2400000027	A. BUILDING _____ B. WING _____	C 09/24/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LOMA LINDA UNIVERSITY MEDICAL CENTER	11234 ANDERSON ST LOMA LINDA, CA 92354

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	Initial Comments The following reflects the findings of the California Department of Public Health during the investigation of entity reported incident. Representing the California Department of Public Health: [redacted]HFEN [redacted]HFEN [redacted]HFES The inspection was limited to specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.	E 000	Plan of Correction	
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 interview and record review, the hospital ' s operating room team for Patient 1 failed to implement the hospital ' s policies and procedures regarding counting surgical sponges. As a result, a surgical sponge was left in Patient 1 during a liver transplant surgery. The patient had to undergo an additional surgery to retrieve the retained sponge from her abdomen twelve hours later.	E 347	E 347 - Surgical Service General Requirements a) **How the correction will be accomplished, both temporarily and permanently** • The policy was changed to require that there be documentation in the Perioperative Documentation Record of each count done (previously only the final count was documented in the permanent record). • As an immediate temporary measure, the information that counts were done was recorded in the narrative portion of the record. Within a month, stamps were obtained to provide a place to document the information. The forms were then modified at the next printing to provide a place to document counts; including initials of persons counting, time of count, and type of count.	

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E 347	Continued From page 1 Findings: Clinical record review on 8/26/08 revealed that Patient 1 was admitted to the hospital on 8/12/08 with diagnosis of liver failure and scheduled for a liver transplant surgery. Review of the Perioperative Documentation Intra Operative form dated 8/14/08, revealed that the liver transplant surgery for Patient 1 started on 8/14/08 at 4:28 PM and ended on 8/15/08 at 2:24 AM. The operating room staff included two surgical technologists (Scrub A and B), Scrub A was orienting Scrub B during the surgery. There were also two circulating registered nurses (RN 1 and RN 2), RN 1 was orienting RN 2 during the surgery. On the Perioperative Documentation Intra Operative form, under "Final Count," "correct" was circled for sponges. There was no other documentation regarding how many counts were conducted. Review of the " OR Count Record " dated 8/14/08, revealed under the title " R.O. 4X4 " (radio opaque 4 inch by 4 inch sponges that can be seen by an X-ray), there were two columns. One column had the heading " In " and the number " 40 " was handwritten under it. The other column had the heading " Out " with two columns under it. The number " 40 " was handwritten in the middle of both columns. There was only one count of " In " and one count of " Out " noted for all of the sponges on the OR Count Record.	E 347	• All OR staff were educated about the requirement before the next shift worked. • The procedure in effect at time of survey required that counts (numbers) of items entered to the sterile field be immediately recorded on the count sheet/white board, as well as the final counts (totals). It has since been decided to require that the numbers of interim counts also be recorded, and the procedure has been modified. The count sheet/white board is for use during the surgery only, and is discarded/erased at the end of the case. • OR staff will be informed of the change and monitoring done to ensure compliance **c) The title of the person responsible for the correction** Executive Director, Perioperative Services **d) A description of the monitoring process to prevent recurrence of the deficiency** • A random sample of at least 20 cases done in the Medical Center OR has been audited monthly from August 2008 through March 2009 to confirm that sponge counts were done at personnel changes (counts at other portions of the cases were audited previously). From November 2008 through March 2009, the audits also included evaluation of whether the counts were documented. Compliance has been 96% or greater, with 100% compliance since December 2008. Audit will now be done less frequently (at least every 6 months) to confirm continued compliance – returning to monthly intervals if compliance is found to decrease.	

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E 347	Continued From page 2 On 8/15/08 3:38AM, a chest x-ray was performed to check the placement of a central line catheter (an intravenous line placed into a large vein near the heart). The x-ray impression was "possible retained sponge below the left hemi diaphragm (half of the diaphragm)" The x-ray was repeated on 8/15/08 at 10:30 AM, and the impression was " redemonstration of a radiopaque marker ...consistent with a retained surgical sponge. " Review of the Operative Report dated 8/15/08, revealed a reexploration of the abdomen for removal of sponge was perfonmed. " A small Ray-Tec sponge in the left upper quadrant between the stomach and diaphragm " was found and removed. " Review of the hospital's Administrative Technique policy and procedure (P & P) titled " Sponge, Sharp and Instrument Count " dated 3/08 revealed that " it is mandatory that all counts be done by both scrub person and circulating nurse ...Counts must be recorded immediately. Sponge counts are taken: before the procedure to establish a baseline, before the closure of a cavity within a cavity, before wound closure begins, at skin closure or end of procedure, and at the time of relief of either the scrub person or the circulating nurse...Write total of count as soon as possible after counting." During an interview with the Executive Director of Perioperative Services on 9/16/08 at 10:10 AM, he stated the OR Count Record is not a part of a patient's medical record. It is used as a worksheet or a working tool and when the surgery is completed, the count record is sent to the	E 347	• At least 30 cases per month will be monitored at the Medical Center OR (20 at each other site) beginning in August to ensure that interim count numbers are recorded on the count sheet/white board until consistent compliance is established. Monitoring will then be done less frequently (at least every 6 months) to confirm continued compliance – returning to monthly intervals if compliance is found to decrease. **d) The date the immediate correction of the deficiency will be accomplished** • The requirement that there be documentation in the Perioperative Documentation record of all sponge counts was implemented on September 22, 2008. • Immediate staff education regarding the requirement to document that each sponge counts are done was provided in September 2008 (beginning 9/22/08), with staff educated prior to first shift worked beginning with that date. • Re-printing of forms with an area for documentation of counts was done by March, 2009. • Staff will be educated regarding the requirement to record all counts on the count sheet/white board. Instruction will be given at the beginning of each shift via paper instructions and discussion, starting July 20th – to be completed by July 31. Staff will be expected to implement this on the day instructed. Staff not working during these days will be educated on return to work.	

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billing department. He stated that there is no way to go back and check the counts that were done during any surgery.

During an interview with the Operating Room Nurse Manager on 9/16/08 at 11:01 AM, she stated " for the most part, they (operating room circulating nurses) use the worksheets.

During an interview with the Operating Room Assistant Nurse Manager on 9/16/08 at 11:15 AM, she stated that due to the complicated cases handled by the department, the Operating Room Count Record is a worksheet but is required to be filled out by staff on every surgery or procedure. However, there is no way to look if the counts had been done because the Operating Count Record is not included in the patient ' s medical record.

During an interview on 9/18/08 at 3:03 PM, the Operating Room Nurse Educator stated that the OR Count Record is a worksheet and staff must fill it out for every surgery.

During an interview on 9/17/08 at 2:25 PM, Scrub A stated that the counts are documented on the OR Count Record. She confirmed that the " 2nd count " , meaning the count prior to skin closure, was not documented on the count record.

During a telephone interview on 9/17/08 at 3:20PM, RN 1 stated that she could not confirm that the count was accurate due to not having the count record in front of her. She stated that " Ray-Tec (sponge)s can be easily lost " and she tries to maintain a count of them.

During an interview on 9/24/08 at 11:10 AM, the OR Chief of Staff stated that Ray-Tec 4x4 ' s should not routinely be used in abdominal cases,

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E 347	Continued From page 4 and if they are, they should be used with a sponge stick, which is a sterile forceps to prevent retention of the sponge. Review of the documentation failed to show that the P & P " Sponge, Sharp and Instrument Count " was implemented. Due to the retained surgical sponge after a liver transplant surgery, Patient 1 had to undergo an additional surgery which placed the patient at risk for infection and other complications. This violation has caused or is likely to cause serious injury or death to the patient.	E 347		