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
	050022	A. BUILDING _____ B. WING _____	12/03/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RIVERSIDE COMMUNITY HOSPITAL	4445 MAGNOLIA AVENUE, RIVERSIDE, CA 92501 RIVERSIDE COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00205916, CA00201465 - Substantiated Representing the Department of Public Health: Surveyor ID # 21211, 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. The facility's failure to ensure that a fourteen (14) centimeter metal clamp inserted into Patient 1's abdomen during an open surgical procedure on [redacted] 2009, was detected and removed is a 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 and Safety Code section 1280.1. Abbreviations Used: Cm - centimeter CT - Computerized Tomography OR - Operating Room RN - Registered Nurse		Summary of Events: Riverside Community Hospital (RCH) first learned of the retained foreign body on 9/9/09. RCH self-reported to CDPH on September 11, 2009. RCH reported this incident to the Joint Commission as a sentinel event on 9/11/09. A root cause analysis (RCA) was performed and was submitted to The Joint Commission (TJC) on10/23/2009. On January 8th, 2010, RCH received a notice of acceptance of the RCA with a requirement to perform follow-up monitoring and to submit the measures of success (MOS) by May 8th, 2010 (see attachment #1). The discussion of the open sentinel event review was noted in Board Meeting Minutes from September 23, 2009 and December 2, 2009 and at the Quality & Safety Meeting minutes of January 12, 2010 (attachment #2). Monitoring was performed for the months of Jan 2010-April 2010. These were performed and submitted to TJC prior to the May 8th deadline. On May 27th, 2010, RCH received notice from TJC that the required monitoring data submitted was acceptable and that there was"effective resolution of this sentinel event" (attachment #3).	

Event ID:QJ0911 3/21/2011 5:46:00PM

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Peter D. Bullot	CEO	04/12/2011

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	Continued From page 1 VP - Vice President --- E347 T22 DIV 5 CH1 ART3- 70223 (b)(2) (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. Based on interview and record review the facility failed to ensure surgical policies regarding instrument count were implemented resulting in a retained surgical instrument in Patient 1. Findings: 1. On [redacted] 2009, the facility reported a retained surgical instrument which was discovered in Patient 1 who had an initial surgical procedure on [redacted] 2009. A review of Patient 1's record was conducted on September 17, 2009 and December 2, 2009. According to the emergency room treatment summary dated [redacted] 2009, Patient 1 presented to the emergency room with severe general		There was a special Medical Executive Committee (MEC) and Board meeting held on March 30, 2011 to review the event that happened in 2009, the receipt and content of the CMS letter, corrective actions taken in 2009 and monitoring completed in 2010; and corrective actions and monitoring as a result of the CMS letter (attachment #4). Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. E347-T22DIV 5 CH1 ART3-70223 (b)(2) Riverside Community Hospital (RCH) has a house-wide Performance Improvement Plan, IND 146, which describes our goal as continuing to improve performance and patient safety ultimately reducing the risk to patients (see attachment #5). The performance improvement & patient safety plan provides the framework for Riverside Community Hospital to systematically design, assess, monitor and improve processes, structures, outcomes and patient safety by utilizing the principles of continuous quality improvement.	

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	Continued From page 2 abdominal pain. [redacted] denied a history of general abdominal pain and [redacted] had never had abdominal surgery. A physical examination in the emergency room by Physician 1 indicated that Patient 1 had general abdominal tenderness and no bowel sounds. Patient 1 was taken into surgery that same day, [redacted] 2009. According to the operative/procedure note dated [redacted] 2009, Physician 3 performed a sigmoid colostomy and an end colostomy under general anesthesia on Patient 1. The operative/procedure note stated "all lap and instrument counts were correct." Clinical record review at an imaging center, unaffiliated with the facility, revealed that a CT scan of the abdomen and pelvis dated September 4, 2009, was performed on Patient 1. The findings stated, "IMPRESSION" 14-cm metallic instrument, probably a hemostat, in the right lower quadrant." The History section of the CT report states that the patient had surgery on [redacted] 2009, and "Patient has been experiencing abdominal pain around the belt line anteriorly since that time." The CT scan report also stated, "These findings were discussed with Physician 4 at 9:00 a.m. on September 4, 2009." Patient 1 returned to the facility on [redacted], 2009, for a Colostomy takedown (13 days after Physician 4 was made aware of a retained foreign object in Patient 1's abdomen).		RCH facilitates an environment which: o Encourages recognition and acknowledgement of risks to patient safety and medical health errors; o Initiates action to reduce risks; o Encourages internal reporting of identified opportunities and actions taken, including actual errors and near misses; o Focuses on processes and systems and minimizes individual blame or retribution for involvement in a medical / health care error; o Encourages organizational learning about medical health care errors to effect behavioral changes in the environment.	

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	Continued From page 3 A review of the facility document entitled "History and Physical dated [redacted] 2009," the section titled "HISTORY OF PRESENT ILLNESS :" stated .... "The patient presented to me" (Physician 4) "on [redacted] of this year for take down of his colostomy and restoration of intestinal continuity" and "Because [redacted] was also having complaints of pain in [redacted] abdomen, ultrasound of the gallbladder was performed which does demonstrate a gallstone and CT scan of the abdomen and pelvis performed which unfortunately showed a large metal clamp left in the abdominal cavity." On [redacted] 2009, Patient 1 returned to surgery. A review of the surgery report dated [redacted] 2009 indicated the operation performed. "Colostomy takedown," (reconnecting the colon), "colorectal anastomosis," (connecting the colon back to the rectum), "cholecystectomy," (removal of the gallbladder) and "removal of foreign body (metal clamp) with lysis of adhesions," (releasing of a fibrous band or structure by which parts abnormally adhere). Further review of the surgery report indicated, "A Kocher clamp was encountered within the abdominal cavity, extending anteriorly into the lower abdominal wall to the left of the midline. It attached itself to the serosal surface of several loops of distal ileum." The clamp needed to be freed from these loops by sharp dissection, which was done. In an interview with the Operating Room director on September 17, 2009 at 11:30 a.m., she stated,		The Quality and Safety Committee is a medical staff committee composed of key Medical Staff and hospital leaders that have the responsibility to the Medical Executive Committee and the Board of Directors for: • Establishing priorities for performance improvement, staffing effectiveness and patient outcomes; • Ensuring compliance with National Patient Safety Goals; • Assuring a preventative and proactive approach to care; • Allocating sufficient human, information system, physical and financial sources to support the patient safety and performance improvement program. • Monitoring the effectiveness of performance improvement and patient safety program. • Ensuring a proactive risk reduction actions to be taken to reduce risk and improve patient safety;	

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	Continued From page 4 "there was an error in counting, it was a human error, could not identify in any variables." During an interview with RN 2 on December 1, 2009, at 11:30 a.m., she stated she was the RN present for the initial surgical instrument count, but was relieved by another nurse, therefore she was not present for the final count. During an interview with the Quality and Safety Vice President on December 1, 2009, she stated, according the facility investigation: a count was conducted after Patient 1's skin was closed, the physicians were looking for a surgical instrument, and there was a "disconnect" between the facility staff and Physicians involved in the surgery regarding reporting. The physicians were aware a clamp was not accounted for, however, did not report to facility Administration for follow-up. She further stated, the facility was unable to determine who the scrub nurse or circulatory nurse was at the time of the surgery or "who was doing what in a point of time." She stated the facility was unable to determine or identify who conducted a final count as there were no signatures on the count sheet and the count sheet was not in "real time." A review of the facility's policy and procedure entitled, "Counts - Instruments, Sharps, Sponges" (revised April 2009) stipulated, "...instruments...on the operative field will be counted on every surgical/invasive procedure to prevent retention of foreign objects in the patient...When either scrub person or circulating nurse is relieved-count should be taken by relieving person(s). Any time a hand-off		• Evaluate and revise the patient safety plan at least annually; • Monitor implementation of corrective actions for patient safety events • Make recommendations to eliminate future patient safety events • Assuring intense analysis and implementation of risk reduction actions in a medical / health care error or sentinel event. Based on the nature and severity of the event, a root cause analysis (as part of the PI process) was conducted on 9/14/2009 to determine the causal factors that led to the instrument being left in the patient. Team members who participated in the RCA included the Director of Perioperative Services, Manager of Perioperative Services, VP of Quality & Safety, Director of Risk Management, VP of Patient Care Services, the surgeon who performed the first surgery on the patient, and Operating Room staff involved in the case (3 circulators, 2 scrub techs).	

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	Continued From page 5 occurs a count/report should be performed...Documentation on the Operating Room Nurse's Record will include: 1st, 2nd, Final Counts with the Circulator's initials, and "Relief Count Correct", if applicable...." 2. In an interview with the Operating Room Director on October 20, 2009, at 2:45 p.m., the instrument count sheet for Patient 1 was requested. The Operating Room Director stated, "We didn't save them..." In an interview with RN 1 on October 20, 2009, at 2:15 p.m., she stated a count sheet accompanies the tray with the instruments and further stated a record of the count is recorded on the count sheet. She further stated the count sheet is discarded after the case. In an interview with RN 2 on December 1, 2009, she stated the paper (count sheet) was not saved. During a tour of the sterile processing unit on December 2, 2009, at 4:20 p.m., the supervisory staff stated the instrument count sheet was kept with the OR record. On December 2, 2009, at 4:20 p.m. Patient 1's Instrument Inventory Sheets was provided by the facility. A review of Patient 1's major instruments inventory sheet on December 2, 2009, indicated no number was written in the second column listed as "QTY"		At the time of the first interview (October 2009), the count sheets were not saved as part of the permanent medical record, but were saved in the Sterile Processing Department. Not all staff were aware of this process. After the CDPH survey on October 20th, 2009, changes were made to mandate the staff use the count sheets as their working document to then input into the electronic record. The count sheets are now saved in the Sterile Processing Department. At the time of the survey on December 1, 2009, the revised policy on instrument counts was just starting to be educated to the staff, and therefore they could not speak to the change in process of where the count sheets are saved. As of December 31, 2009, the policy was revised and the staff completed education on the revised count process.	

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	Continued From page 6 (quantity), "OR 1st" (first operating room count), and in the third column listed as "QTY" (quantity), "OR 2ND", (operating room second count) showed only a check mark. Further review of the inventory sheet showed that there were no signatures of the circulating and scrub nurses. The document showed the number of instruments used at the beginning of the surgery but failed to show the number of instruments accounted for after the surgery. In an interview with the Quality VP on December 1, 2009, at 2:30 p.m., she stated it was difficult to pinpoint who was the scrub and circulating nurse, who was doing what in a point of time and was unable to identify who did the final count. There were no signatures, no actual signatures. A review of facility policy and procedure titled, "COUNTS- INSTRUMENTS, SHARPS, SPONGES" section "III Procedure" states: "H. INSTRUMENTS" "7. Counts sheets will be signed by the scrub person and RN after completing the baseline/initial count. The facility's failure to ensure implementation of their policy and procedure on counting instruments on the operative field on a surgical/invasive procedure of Patient 1 is a deficiency that has caused, or likely to cause, serious injury or death to the patient and therefore constitutes an immediate jeopardy within the meaning of Health		Therefore, the corrective actions taken as a result of the root cause and CDPH surveys were: A. Policy & Procedure IND210-- Counts, Instruments, Sharps, and Sponges -- was revised and updated on September 11, 2009 to describe the count process and requirement for adherence to consistent practice. (attachment #6) **Responsible person**: Director of Perioperative Services & OR Management Team **Completion date**: the policy was approved by Surgical Dept 11/11/09, approved by Medical Executive Committee on 11/17/09, approved by the Board on 2/23/10 as evidenced by the attached meeting minutes (see attachment #7).	2/23/10

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	Continued From page 7 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).		B. Policy & Procedure IND-210 Counts, Instruments, Sharps, and Sponges was reviewed with all surgical staff, and a competency skills validation checklist was required as part of this education. A copy of the competency validation check off list is attached (see attachment #8) **Responsible party**: Director of Perioperative Services & OR Management Team **Completion date**: 12/31/09 **Compliance Monitoring**: sign off list of all staff involved in surgical counts acknowledging receipt and review of the revised policy was implemented by the Director. The Director monitored for completion. 100% of OR staff completed.	12/31/09

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	Continued From page 7 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).		C. The instrument count sheet was reviewed and found to be appropriate (see attachment #9) Scrub tech(s) and RN(s) performing initial and final instrument counts are required to sign the instrument count sheets. **Responsible party**: Director of Perioperative Services & OR Management Team **Completion date**: 12/31/09 with audit Jan-April 2010 **Compliance monitoring:** a random selection of procedures/instrument counts sheets were reviewed the Perioperative Manager for signatures by both the scrub tech and RN. A minimum of 70 records were reviewed for 4 months (Jan – April 2010). The audit results for Jan – April 2010 were 100% each month (see attachment #10).	12/31/09

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	Continued From page 7 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).		Results were presented to the MEC and the Board by the VP of Quality at the March 30, 2011 meeting (attachment #4). This audit will be reinstituted by the OR Manager for a period of three months. Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. D. The primary circulator has been designated as the person doing the counts if she/he is present in the room (i.e. not on break). If the circulator or scrub person is relieved for break, a handoff communication occurs, including information on counts. The person relieving the other reports to the scrub or circulator every item added on to the field during their absence (when possible, save the wrappers as supporting information). If the scrub or circulator is permanently relieved, a full count is done by the oncoming relief scrub teach and RN.	12/31/09

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	Continued From page 7 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).		Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. E. The final closing count, including instruments, is performed visibly and audibly by the scrub tech and RN at the completion of skin closure. The count is not considered complete, and correct, until all instruments, sponges, and needles are removed from the sterile field and accounted for. **Responsible party**: Director of Perioperative Services & OR Management Team **Completion date**: 12/31/09 with audit Jan-April 2010 **Compliance monitoring:** observation by the Perioperative Manager of scrub tech and RN performing the final count audibly and visibly together. A minimum of 70 cases /month for 4 months was performed.	12/31/09

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050022	A. BUILDING _____ B. WING _____	12/03/2009

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	Continued From page 7 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).		The audit results for Jan – April 2010 were 100% each month. (see attachment #10) Results were presented to the MEC and the Board by the VP of Quality at the March 30, 2011 meeting (see attachment #4). This audit will be reinstituted by the OR Manager for a period of three months. Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. F. Competency validation check off sheet (attachment #8) was added as part of the Operating Room orientation. This is signed off by the preceptor. The preceptor has been specifically educated by the OR Educator on the process for orientating new employees to the count procedure and assuring the procedure is followed accurately to the policy. **Responsible party**: Director of Perioperative Services & OR Management Team	12/31/09

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	Continued From page 7 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).		**Completion date**: All current staff were completed by 12/31/09 **Compliance Monitoring**: All new employees will complete this competency within 30 days of hire. This is completed by the OR Educator and place in their files. An audit was conducted of 100% of new OR employees hired after 1/1/10 to ensure that the competency was completed in the required timeframe (see attachment #11). Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. G. Scrub tech(s) an/or RN(s) performing initial and final instrument counts are required to document each time they count in the electronic medical record (see attachment #12) **Responsible party**: Director of Perioperative Services & OR Management Team	3/30/11

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	Continued From page 7 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).		**Completion date**: March 30, 2011 **Compliance monitoring:** a random selection of procedures/instrument counts will be reviewed by the Perioperative Manager for documentation in the electronic medical record. A minimum of 70 records will be reviewed for 3 months. (see attachment #12) Results of all monitoring activities will be forwarded monthly to the Quality & Safety Committee, MEC, and Board, by the VP of Quality. H. To educate physicians on serious reportable events and their obligation to report them to the RCH Management or Administrative Teams—an educational flyer was distributed via broadcast fax to all physicians on staff by the Medical Staff department on December 31st, 2009.	12/31/09

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	Continued From page 7 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).		In addition, the flyer was presented and discussed at the Quality & Safety Meeting on 1/12/2010 (see attachment #2). The President of the Medical Staff presented the letter again at the quarterly Medical Staff meeting on January 25th, 2010 (see attachment #13 for meeting minutes). **Responsible party**: Vice President of Quality & Safety, President-Medical Staff **Completion date**: 12/31/09 In addition to the above actions, RCH engaged the services of the ECRI Institute to assist us with assessing our culture of safety in the Perioperative area. The ECRI Institute is an independent nonprofit organization that researches the best approaches to improving the safety, quality, and effectiveness of patient care. A survey was done in the third quarter of 2010 to assess the culture of safety and the results were shared with the staff.	

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