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
	050128	A. BUILDING _____ B. WING _____	04/27/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Tri-City Medical Center	**4002 Vista Way, Oceanside, CA 92056-4506 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: CA00425153 - Substantiated Representing the Department of Public Health: Surveyor ID # 27942, 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 1280.3: 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 & Safety Code Section 1279.1 (a) (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. Health & Safety Code Section 1279.1		**Penalty Number 080011423** The plan of correction is prepared in compliance with federal regulations and is intended Tri-City Medical Center (the "hospital") credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the, citations are correct or that it violated the law. **Health & Safety Code 1279.1 (a)** 1. Temporary corrective actions taken: a. The involved staff members (2) were placed on administrative leave pending a full investigation into the process for not following the policy for "counting of sponges and other items" following a procedure. b. The patient received full disclosure. c. The RN was terminated. d. The scrub tech was suspended without pay for 3 days. e. RCA which included all the involved staff/surgeons was conducted. f. Case sent forward for peer review g. Responsible Party: SR Director of Medical records h. Date: 12/31/2014 i. Permanent Corrective Actions: All nursing staff and surgical techs were re-educated on "leave nothing behind" and the counting process / bagging of sponges & final count to be done before patient leaves the OR.	

Event ID:VGTZ11 4/29/2015 8:33:50AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Jami Gleason 5/5/15 TITLE Director Regulatory Compliance (X6) DATE

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 7

Any deficiency statement ending with an 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.

Clarence 5/8/15

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	(b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events including the following: (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. . Health and Safety Code Section 1279.1 (c) (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 adverse event by the time the report was made. 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 California Code of Regulations, Title 22, 70223(b)(2). Surgical Service General Requirements: A committee of the medical staff shall be assigned responsibility for:		j. Monitoring process by the leadership team put into place. The scrub tech must call a member of the OR leadership team or their designee for the purpose of verifying correct count before the patient leaves the OR. This process was put into place for approximately 4 months to ensure that the staff was adhering to TCMC current "counting" policy. All occurrences in which the leadership team determined staff was not following current policy involved a coaching/counseling opportunity for the involved staff. k. The compliance for the "double" check by leadership was presented to the Joint Commission Committee and to the QAPI & OR Committee monthly. Once we have determined that the counts are being done per policy the "interim" monitoring by leadership will conclude with random double checks by the leadership team from the OR. l. Monitoring Requirements: m. On a daily basis the results of the daily monitoring are presented to the SR Director for Nursing. This report is reviewed to determine if staff is adhering to process.	

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	(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 follow its procedure for the prevention of retained surgical objects for one patient having abdominal surgery resulting in a second surgery and admission to the intensive care unit in critical condition. Patient 1 was admitted to the facility on 12/23/14 via the Emergency Department (ED) for acute abdominal pain and ectopic pregnancy requiring surgery, per the clinical record. On 1/6/15 the clinical record was reviewed with the Director of Regulatory Compliance (RDC). The DRC acknowledged that the ED Report (Dated 12/23/14) indicates Patient 1 presented to the ED complaining of severe abdominal pain and was diagnosed with a ruptured ectopic pregnancy (a pregnancy growing outside of the uterus). Patient 1 was scheduled for immediate surgery. On 1/6/15 the facility Procedure: Sponge, Sharps and Instrument Count, Prevention of Retained Surgical Objects (Dated 11/14) was reviewed with the DRC and the Director of Surgical Services (DSS). The DRC and the DSS acknowledged that the procedure indicates that countable items		n. This report is reviewed for non-compliance and submitted to the QAPI & Joint Commission Committee monthly. o. The counting/UP was added to our "Tracer Tool". We have a team that rotates into the OR and other procedural areas to review "actual" counting process to ensure compliance. The results of the "real" time survey are presented to the Joint Commission Committee monthly and to the BOD quarterly. p. Responsible Person: Director for Regulatory Compliance q. Completion Date: Ongoing	

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	include Lap Sponges (Large surgical sponge commonly used in abdominal surgeries). The procedure also indicates that sponge counts shall be performed as follows; a Baseline count at the beginning of the case, a New Item count if anything new is added to the case, a Relief count if the operating room technician (ORT) or nurse (ORN) is relieved during the case, a Cavity count before the closure of an internal cavity (as in abdominal surgeries), a Closing count when wound closure begins, and a Final count at the end when the skin has been closed. On 1/6/15 at 11:30 A.M., during an interview, Operating Room Nurse 1 (ORN 1) stated, "I've been an O.R. Nurse for 26 years. Counts are done before the surgery begins, during, and afterwards any time the incision is big enough for anything to get into the wound. Lap sponges are counted at the beginning, if you add any to the case, when you close each cavity and the skin, and at the end of the case. It's done for patient safety. You don't want to leave any foreign object in the body after surgery because it could cause an infection." ORN 1 continued, "At the end of this case (Patient 1) the surgeon was done closing the cavity and skin before the Cavity count was done." ORN 1 further stated, "The surgeon finished closing the wound before we had the Cavity count done and he left the room. The patient started to wake up, people were starting to come in to turn-over (clean up) the room, and the Charge Nurse phone rang, so I left the room to answer it, I felt rushed. The scrub tech. (ORT 1) was still looking for all the sponges when anesthesia moved the patient out to PACU			

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	(recovery room). I assumed the counts were completed." ORN 1 then stated, "The skin count and the final count had not been done when the patient left the O.R." On 1/6/15 at 12:30 P.M. during an interview, ORT 1 stated, "I've been a scrub tech (ORT) for 4 years. Counts are done to ensure that nothing is left behind inside a patient that could hamper recovery, cause damage and an infection. We count sponges at the initial count, if we add any during the procedure, when we close the cavity, when we close the skin, and at the end of the case. The final count needs to be complete before the patient leaves the O.R." ORT 1 further stated, "After the Cavity count was done I was still missing two lap sponges. I began looking for them and said out loud that I was missing two sponges while the patient (Patient 1) was still in the O.R. I was still searching for the two sponges when that patient (Patient 1) was moved to the PACU (Post Anesthesia Care Unit or recovery room)." ORT 1 continued and stated, "At the end of the case nobody stopped as I looked for the laps (sponges) and voiced multiple times and loud enough for everyone to hear 'I'm missing two laps." On 1/5/15 at 2 P.M., during an interview, ORT 2 stated, "I've been an O.R. Tech for 15 years. I saw her (ORT 1) searching the room and trash after the case was done. She said she had lost 2 sponges. She said the count was correct but the sponge holder had two empty places in it. The count was 'incorrectly correct'. The count could not have been correct and the patient (patient 1) should not have			

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	left the O.R. room if the count was not correct. The team should stay until the count is confirmed." On 1/6/15 at 2 P.M., during an interview, the DSS stated, "The patient is not to leave the O.R. room until the counts are complete and correct. Unfortunately, that didn't happen in this case." On 1/6/15 at 2:15 P.M. during an interview, Patient 1's physician Anesthesiologist (ANA) stated, "I listen for the count and then start the transition to move the patient. I only listen for one count then I concentrate on the patient and moving them. No one ever told me to stop." On 1/6/15 at 2:30 P.M. during an interview, Patient 1's Surgeon (MD 1) stated, "I packed the bowel with two lap sponges early in the case. I examined everything, the uterus and fallopian tubes; everything looked okay except for the ectopic. It was a very routine case; she should've gone home after a couple of days." On 1/6/15 at 3 P.M. during a record review and interview the second surgeon (MD 2) acknowledged that she was emergently consulted on December 25th at 5:30 P.M. for Patient 1, who had an acute change (worsening) of condition with abdominal sepsis (a critically unstable infective process). After emergent surgery Patient 1 required a breathing tube with mechanical ventilation (Breathing machine) and was sent to the intensive care unit, per the consultation and post-operative report. MD 2 further stated, "I was the surgeon for (Patient 1) the second case. The nurse on the floor			

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	called me to report that the patient was complaining of acute increased abdominal pain. I ordered a CT (a specialized x-ray) of the abdomen and some lab work. She (Patient 1) was very sick, she had a severe infection and the CT revealed that there were likely two foreign bodies in her abdomen. I took her straight to surgery." MD 2 further stated, "In surgery I removed what appeared to be two lap sponges, and during an inspection of her abdominal cavity, determined that the inflammatory process as a result of the foreign objects had done significant damage to nearby organs. I had to remove her ovaries, remaining fallopian tube, and uterus, a total hysterectomy. She (Patient 1) remained intubated and on a ventilator and was sent to the ICU (Intensive Care Unit)." As a result of the hospital's failure to follow its surgical count procedure, Patient 1 suffered a second surgery, resulting in the removal of her ovaries, remaining fallopian tube, uterus, and cervix - a total hysterectomy, and admission to the intensive care unit in critical condition. 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).			