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
	CA050000039	A. BUILDING _____ B. WING _____	C 07/10/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VENTURA COUNTY MEDICAL CENTER	3291 LOMA VISTA RD VENTURA, CA 93003

(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, Licensing and Certification, during the investigation of an entity reported ADVERSE EVENT. ADVERSE EVENT # CA00192993 Representing the Department: [redacted] HFE-N The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.	E 000	Preparation and execution of this plan of correction does not constitute admission or agreement of the facts alleged. It is being prepared solely because it is required by Federal and State law.	
E 271	T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures. (d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. This Statute is not met as evidenced by: Based on staff interview, medical record review, and facility policy and procedure review the facility failed to implement its written polices and procedures to ensure that sponges, sharps and instruments, used during surgical procedures, are accurately accounted for. Patient A had abdominal surgery on [redacted]/09. Post operatively Patient A developed increased abdominal pain, nausea, vomiting, and a swollen abdomen. A second surgery on [redacted]/09 revealed a surgical towel was left in the patient's abdomen and was removed. Surgical staff failed to provide safe practices for Patient A by failing to ensure the	E 271	E271: Please see page 2 for corrective action CA DEPT OF PUBLIC HEALTH 2011 JUN 27 AM 10:41 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE 7/19/2011 Poc Accepted. Lynda Cole 6/22/11	

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE Chief Nurse Executive — (X6) DATE

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E 271	Continued From page 1 scrub technician and the circulating nurse audibly and visually accounted for the use of the surgical towel. In addition, the perioperative record dated [redacted]/09 lacked the signature of the participating scrub technician, verifying the results of the counts with the circulating nurse, as required per facility policy and procedure. Findings: Review of the facility's policy and procedure titled "Accountability for Sponges, Sharps, and Instruments" Purpose "To provide guidelines of accountability for sponges, sharps, and instruments uses during a surgical procedure. To provide safe practice for the surgical patient, prevent patient injury and adhere to legal standards." The policy stated in part... "all counts shall be audibly and visually performed according to procedure by the circulating nurse and scrub nurse." The circulator may allow another licensed nurse to count with the scrub nurse, but the name of the licensed person must appear on the Peri-Operative record. The circulating nurse and scrub nurse shall document and sign the Peri-Operative Record with the results of the counts. Patients are not to leave the Operating Room until missing items are accounted for." Clinical record review beginning on 6/29/09 at 9:00 a.m. revealed that Patient A was admitted to the hospital on [redacted]/09 for a scheduled laparoscopy, possible laparotomy, to close a colostomy (opening in to abdomen to divert feces). A laparotomy with closure of the colostomy was completed and the patient was discharged home on [redacted]/09. According to the Operative Room Nursing Record dated [redacted]/09, three registered nurses (RN 1, 2,	E 271	2011 JUN 27 AM 10:41 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE CA DEPT OF PUBLIC HEALTH E271- Policy was reviewed that relates to documentation on the surgical record. Education was provided to all circulating nurses in the OR related to proper documentation, which includes documenting the "initials" of the OR scrub tech. The improper documentation of "ST" short for scrub tech was discussed and all staff were reminded that this is an inappropriate documentation. The OR Director and Nurse Manager are responsible to audit this on the surgical record. For on-going quality improvement these audits are presented at the Surgery Committee meeting on a quarterly basis. This process was completed in September of 2009 and we continue to audit the surgical record as of now.	Sep 2009 Jun 2011

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E 271	Continued From page 2 3), two surgical technicians (ST 1, 2) and a student surgical technician were in the operating room, at various times during the surgical procedure. RN 1 was assigned the primary responsibility for circulating the procedure and ST 1 was the primary scrub technician. The documentation of the counts, recorded on the [redacted]/09 OR Nursing record RN 3 did the initial count. RN 1 did the 1st and 2nd counts, and RN 2 did the final count. According to the documentation all counts were correct. Further review of the count verifications revealed that the only count initialed by the surgical technician(s) as accurate was the initial count with RN 3. The subsequent counts (1st, 2nd and 3rd), although initialed by RN 1 and RN 2, had only "ST" written in the verifying column where the scrub nurse/tech would document their initials. In an interview with DON on 6/30/09 she stated that the letters "ST" were recorded in the scrub nurse/technician column by RN 1 because she was not sure of the name of scrub tech she and RN 2 had verified the counts with. There was no documentation to indicate the surgical technicians documented and signed the Peri-Operative Record with the results of the 1st, 2nd and 3rd counts verifying the accuracy of the counts, as required by facility policy and procedure. On [redacted]/09 Patient A presented at the emergency department with complaints of increased abdominal pain, nausea, vomiting, and abdominal bloating. Radiological studies done at this time showed a distended bowel and a "swirl-like material" and a "band-like foreign body." Patient A had a second abdominal surgery on [redacted]/09. According to the postoperative diagnosis on the operative report Patient A had an..."abdominal	E 271	E271- VCMC did a complete review of this incident immediately upon discovery. We interviewed all staff involved, as well as the surgeon and anesthesiologist. We discovered that there were processes that could be improved on. While everyone in the room during the surgical procedure agreed that the count was correct and followed the policy for counting, there were system issues that did not prevent the towel from being left in. We reviewed our policy for counting and made revisions to the policy. The surgery nurse manager and the Chief Nurse Executive provided inservice education to all staff who circulate or scrub in a surgical case regarding the change in the process for counting, which included new white boards in each room to document every single thing that is entered into the surgical field. Towels had not been listed on the count board prior to this and it was felt that by providing a tool to document a towel in the field staff would be aware to include this in the final count. This process is audited by the OR Director and Nurse Manager, randomly on a weekly basis. This continues to be a focus of audits as of	√ Sep 2009 Jun 2011

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E 271	Continued From page 3 mass post colostomy takedown secondary to a radiopaque towel with small bowel perforation and incidental rectosigmoid perforation. Abdominal abscess secondary to radiopaque towel in the right mid abdomen and small bowel deserosalization x 2." Interview with surgical technician 1 (ST 1) on 6/29/09 at 11:00 a.m. confirmed that he was the primary scrub technician for Patient A's abdominal surgery on [redacted]/09. ST 1 stated he remembers holding up two surgical towels and audibly counting "one", "two." However, he could not recall which RN counted with him, or whether the surgical towels were written on the white board as added to the count. There was no documentation to verify that all counts were audibly and visually performed and recorded on the surgical board, according to procedure by the circulating nurse and scrub nurse. During an interview on 6/30/09 at 2:30 p.m. RN 1 confirmed that she was assigned the primary circulating duties during the Patient A's surgery on [redacted]/09, and that she was responsible for ensuring that the sponge counts were correct. She stated RN 3 completed the initial count (prior to surgery), she (RN 1) completed the 1st and 2nd counts, and RN 2 completed the 3rd count. RN 1 stated she did not count any surgical towels with ST 1. Interview with RN 3 on 7/9/09 at 10:00 a.m. verified that she completed the initial count with ST 1 before the procedure started and wrote the number of sponges on the white board in the surgical room. She stated she did not count in any surgical towels with ST 1. Interview with RN 2, on 6/29/09 at 9:30 a.m.,	E 271	E-271 VCMC's procedure for counting was reviewed and re-education of staff occurred. This was done to be certain that all staff members who participate in the count process, as well as the surgeons follow the proper process for counting. Making sure that time is given for the count to be carried out and that all members of the team agree with the count. We also determined that having staff take breaks during a procedure might lead to weaknesses in the process, so altered the process for breaks to be sure that the surgeon agrees the timing of a break doesn't cause any difficulty in maintaining process. There was a nurse who started the procedure and a different nurse who ended the procedure. Our policy for counting when a relief circulating nurse takes over was ammended to include the process of checking with the surgeon prior to a break occurring. The OR Director and Nurse Manager are responsible for auditing cases as the are going on to determine the process established is being followed. This was completed in September of 2009 and continues now.	Jun 2011.

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E 271	Continued From page 4 revealed he came into the room to help RN 1, but did not relieve her. He stated that he did the third count (after the skin was closed) with ST 2 and the student surgical technician. The count was correct with the number of sponges recorded on the white board. He denied adding any surgical towels to the operative field. On 6/30/09 at 3:00 p.m. an interview with surgical technician 2 (ST 2), revealed he relieved ST 1 at the end of the procedure. The 1st and 2nd counts were already done when he entered the room, and ST 1 had already left the room. ST 2 stated ST 1 did not give him a report or count sponges with him prior to leaving the room. He stated although he was scrubbed as part of the surgical team, he only supervised the student technician who was already there.	E 271		
E 276	T22 DIV5 CH1 ART3-70214(a)(2)(A) Nursing Staff Development (a) There shall be a written, organized in-service education program for all patient care personnel, including temporary staff as described in subsection 70217(m). The program shall include, but shall not be limited to, orientation and the process of competency validation as described in subsection 70213(c). (2) All patient care personnel, including temporary staff as described in subsection 70217(m), shall be subject to the process of competency validation for their assigned patient care unit or units. Prior to the completion of validation of the competency standards for a patient care unit, patient care assignments shall be subject to the following restrictions: (A) Assignments shall include only those duties	E 276	E276-Review of the process for evaluating competency of nurses in the OR was reviewed. The process was altered as it didn't seperate the intial competency evaluation from the speciality competency assessment. All Circulating nurses who work in the OR are required to complete the initial competency assessment related to basic working in the OR related to circulting now. Then as they are exposed and become competent to do speciality cases they complete a seperate competency. This is audited by the OR Director and Nurse Manager. The files are reviewed annually for completness.	Jan 2010

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E 276	Continued From page 5 and responsibilities for which competency has been validated. This Statute is not met as evidenced by: Based on staff interviews and review of two personnel files the facility failed to ensure staff competency was validated, before being assigned the duties and responsibilities of a circulating nurse. Findings: Patient A was admitted for an elective surgical procedure on [redacted]/09 to remove a colostomy (reconnect the bowel from an opening in the abdomen to the patient's rectum to restore normal bowel function). The patient was discharged home five days later. Patient A presented to the emergency room complaining of nausea, vomiting, increased pain and abdominal bloating on [redacted]/09, 16 days after the initial surgery on [redacted]09. Diagnostic studies were inconclusive and Patient A was returned to surgery on [redacted]/09. A review of Patient A's operative record, dated [redacted]/09, on 6/29/09 at 9:00 a.m. revealed RN 1 was assigned the primary responsibility for Patient A's abdominal surgery as the circulating nurse. RN 3 was in the room with RN 1 at the start of the procedure, and RN 2 came into the room to assist the primary circulating nurse (RN 1) almost 2 hours after the surgery began. Review of RN 2's personnel file on [redacted]/09 at 11:30 a.m. revealed he was hired to work in the operating room a year ago, but had no previous	E 276		

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E 276	Continued From page 6 surgical nursing experience. There was no documentation to verify that he received orientation to the surgical suite, or that he was verified as competent to perform circulating duties, before being assigned cases to do independently. Interview with RN 2 on 6/29/09 at 9:30 a.m. revealed he was hired about "a year ago." After he completed the orientation to the operating room he was "turned loose" to circulate independently. RN 2 stated that he was not in the operating room for the entire procedure on [redacted]/09. He stated that he only completed the final count (when the skin was closed), which was correct with the number of sponges recorded on the white board in the room. A review of RN 1's personnel file on 6/29/09 at 11:15 a.m. revealed she was hired to work in the operating room in late 2008. According to the file RN 1's previous experience was working on a medical surgical unit. There was no documentation to indicate that she had previous experience in the surgical department/operating room. There was no documentation to verify that RN 1 had completed orientation to the surgical suite, or that she was competent to perform circulating duties before being assigned cases to do independently. In an interview with RN 1 on 6/30/09 at 2:30 p.m. she stated she was able to circulate independently on "routine surgical procedures." A review of the documentation provided by the facility on 7/6/09 revealed the facility had no competency verification requirements for basic surgical nursing skills, duties and/or responsibilities. The current competency list only addressed the use of specialized equipment and	E 276	E276- As mentioned previously, we have altered our process to have two competency evaluations; one that identifies the basic competency needed to circulate in the OR and the second is for specialized equipment and cases. The Surgical Manager and Director are responsible for auditing all RN's and OR Tech's have completed their competency evaluations. This is an ongoing quality improvement process for the OR. All employee files are reviewed annually for ongoing competency evaluation. As well, any new staff member must complete a basic competency evaluation prior to being allowed to work independently in the OR The OR Director is responsible for ongoing evaluation of this process.	Jan 2010 Jun 2011

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E 276	Continued From page 7 procedures. A telephone interview on 7/9/09 at 10:00 a.m. with the RN responsible for training personnel in the OR verified that the competency checklist was about equipment and special procedures and not about general orientation for surgical skills, duties and responsibilities.	E 276		
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: DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY: T22 DIV 5 CH1-70223(b)(2)SURGICAL SERVICE GENERAL REQUIREMENTS Based on staff interview, clinical record and facility policy and procedure review, the facility failed to implement its policy and procedures to ensure that sponges, sharps and instruments used during surgical procedures are accurately accounted for. Patient A had abdominal surgery on [redacted]/09. Postoperatively the patient developed increased abdominal pain, nausea, vomiting, and abdominal bloating. The patient returned to surgery on [redacted]/09. A retained surgical towel found in the patient's abdomen was removed.	E 347	E 347- Immediately following the incident VCMC began a rigorous review of our practice, policy, and process related to counting of items during a surgical case. We reviewed our policy related to when an xray would be performed, established that this patient missed every element requiring an xray, which is why one didn't occur. Recognizing that by changing our policy to xray a patient if 30 or more lap sponges are used in a case we would provide a better safety process. We altered our policy to reflect that. Also, at the time of this case, the white "count" board did not have an designated area to document the use of a surgical towel. The practice was to "write it" on the whiteboard. When the towels were introduced into the field, the RN did not document them on the board. When we discovered this, during our review, we immediately removed sterile surgical towels from the OR. There was a memo to that affect placed in the OR and everyone made aware of the removal. New white boards were placed in each OR that did list "towel" Once those were up we also located a large "lap towel" that met the needs of the surgeons, (continued on page 9)	

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E 347	Continued From page 8 Findings: Clinical record review beginning on 6/29/09 at 9:00 a.m. revealed that Patient A was admitted to the facility on [redacted]09 for scheduled abdominal surgery. According to the surgeon's operative report the procedures performed included attempted laparoscopic colostomy takedown-converted to open colostomy takedown with coloproctostomy, lysis (cutting) of multiple adhesions, and splenic flexure mobilization. The patient tolerated the procedure well, no complications were encountered and instrument, needle and sponge counts were correct. According to the Operative Room Nursing Record dated [redacted]/09, three registered nurses (RN 1, 2, 3), two surgical technicians, who scrubbed for the surgery (ST 1, 2) and a student surgical technician were in the operating room, at various times during the surgical procedure. RN 1 was assigned the primary responsibility for circulating the procedure and ST 1 was the primary scrub technician. The "OR (Operative Room) Nursing Record" documentation, signed by RN 1, indicated that RN 3 completed the initial counts, RN 1 completed the 1st and 2nd counts and RN 2 completed the 3rd count. The document indicated that all counts were correct. Following surgery, Patient A presented at the emergency department on [redacted]09, thirteen days after the operation, with complaints of increased abdominal pain, nausea, vomiting, and abdominal bloating. Radiological studies done at this time, showed a very distended bowel with a "swirl- like material which may represent stool and possibly ingested material medial to which there is a curvilinear band-like foreign body", however, the tests were inconclusive.	E 347	E-347 (continued) allowing the use of these recognized lap towels instead of a surgical towel once again. The OR Director and Nurse Manager are responsible for auditing the process of surgical counts and related documentation on the white board during a case. This process was completed in Ongoing quality monitoring of this process is still being done as of now.	Jan 2010 Jun 2011.

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E 347	Continued From page 9 Patient A return to the operating room on [redacted]/09 for explorative surgery. According to the operative report findings "a radiopaque towel" was "present in the right mid abdomen/right upper quadrant, with perforation of the mid jejunum with a hole measuring approximately 2 to 3 cm on the antimesenteric border." The towel was "covered partially in succus entericus and had a foul odor to it." The postoperative diagnosis included "abdominal mass post colostomy takedown (of [redacted]/09), secondary to the presence of a radiopaque towel, with a small bowel perforation and incidental rectosigmoid perforation. Abdominal abscess secondary to radiopaque towel in the right mid abdomen. Small bowel deserosalization x 2." The Surgery Department policy and procedure D.1 "Accountability for Sponges, Sharps, and Instrument Counts" was reviewed on 6/29/09 at 2:00 p.m. The purpose of the policy is to "provide guidelines to ensure that sponges, sharps, and instruments used during the surgical procedure are accounted for. To provide safe practice for the surgical patient, prevent patient injury and adhere to legal standards." The policy stated in part "All counts shall be audibly and visually performed according to procedure by the circulating nurse and the scrub nurse... The circulator may allow another licensed person to count with the scrub nurse, but the name of the license person must appear on the Peri-Operative record." The circulating nurse and scrub nurse shall document and sign the Peri-Operative record with the results of the counts..." The procedures stated in part..." Sponges shall	E 347		

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E 347	Continued From page 10 be counted on all procedures involving a major body cavity or the depth and location of the wound as such that a sponge could be retained "... "Sponges shall be counted in the Operating room prior to; and at the closure of the fascia (fibrous tissue supporting the lining of the peritoneum), at the closure of the skin and at the request of the surgeon by the scrub-nurse and the circulating nurse together.." "Additional sponge counts are taken before any part of a cavity or a cavity within a cavity is closed.." Interview with surgical technician 1 (ST 1) on 6/29/09 at 11:00 a.m. confirmed that he was the primary scrub technician for Patient A's abdominal surgical procedure on [redacted]/09. In response to questions he stated that this surgeon was the only surgeon on staff who occasionally used surgical towels on the operative field as packing before inserting a retractor. He stated he remembers holding up two towels and audibly counting "one", "two." However, he does not recall which RN counted with him, or whether the surgical towels were written on the white board as added to the count. During an interview on 6/30/09 at 2:30 p.m. RN 1 confirmed that she was assigned the primary circulating duties during the procedure on [redacted]/09, and was responsible for ensuring that the sponge counts were correct. She stated RN 3 completed the initial count prior to surgery, and RN 2 completed the 3rd count. RN 1 stated she did not add surgical towels to the operative field after the procedure started. During an interview with RN 3 on 7/9/09 at 10:00 a.m. she confirmed that she completed the initial count and wrote the number of sponges on the white board in the room. She stated she did not	E 347		

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E 347	Continued From page 11 count any surgical towels with ST 1. Interview with RN 2, on 6/29/09 at 9:30 a.m., revealed he came into the room to help RN 1, but did not relieve her. He stated that he did the third count (after the skin was closed) with ST 2 and the student surgical technician. The count was correct with the number of sponges recorded on the white board. He denied adding any surgical towels to the operative field. On 6/30/09 at 3:00 p.m. an interview with surgical technician 2 (ST 2), revealed he provided relief of ST 1 at the end of the procedure. The 1st and 2nd counts were already done when he entered the room, and ST 1 had already left the room. ST 2 stated ST 1 did not give him a report or count sponges with him prior to leaving the room. He stated although he was scrubbed is as part of the surgical team, he only supervised the student technician who was already there. Patients in whom a surgical towel is left after abdominal surgery are at high risk for serious complications including pain, infection, abscess, fistula formation, and intestinal obstructions. The facility's failure to ensure that the sponge count was correct, and that no sponges or towels were retained in Patient A following his surgery on [redacted]/09, created a situation that was 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.	E 347		