POC ACCEPTABLE YES NO

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
	050060		09/30/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Community Regional Medical Center	2823 Fresno St, Fresno, CA 93721-1324 FRESNO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00404755 - Substantiated Representing the Department of Public Health: Surveyor ID # 33126, 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. Deficiency Constitutes Immediate Jeopardy Title 22 Surgical Service General Requirements 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.		**The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein.** **This plan of correction constitutes Community Regional Medical Center written credible allegation of compliance for the deficiencies noted.** **Penalty # 040011203** **A. How the correction will be accomplished, both temporarily and permanently. What immediate measures and systemic changes will be put in place to ensure that the deficient practice does not recur;** *On July 09, 2014 after informal notification from Hospital 2 of a retained surgical towel found during surgery on Patient 1, the Surgery department immediately instituted the practice of counting all towels in the operating room.* *On July 10, 2014 after careful review and analysis of the process of counting and utilization of surgical towels a new process was created for the handling of surgical towels.*	

Event ID:NF8I11 1/15/2015 8:46:39AM

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

Karen Buckley RN Chief Nursing Officer 1/20/15

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 13

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.

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	Based on staff interview, clinical record and administrative document review, the hospital failed to develop and implement Operating Room (OR) Policy and Procedure: OR-Counts in the OR, including surgical towels, when the surgery for Patient 1 on 4/8/14 did not reflect the use and count for one surgical OR towel. These failures resulted in Patient 1 suffering an additional hospitalization, a subsequent additional surgery where the OR towel was identified as a retained foreign object, and preventable pain, injury, and harm. Findings: On 7/8/14 The California Department of Public Health (CDPH) received notification from Hospital 2 that they had performed surgery on Patient 1 to remove a foreign body that had been left in Patient 1's abdomen during a prior surgery at Hospital 1. The clinical record for Patient 1 was reviewed for hospitalizations and surgeries. Patient 1 was admitted to Hospital 1 on 4/8/14 for a radical cystoprostatectomy (surgical removal of the bladder and prostate) with ileal conduit urinary diversion (surgical method to divert urine from the bladder by using intestinal [ileal] tissue; the diversion was to a pouch on the outside of the body) performed by Medical Doctor (MD) 1. The discharge summary (dictated by MD 1) and dated 4/16/14 indicated Patient 1 "...Tolerated surgery well ...also had a slightly longer postop [post-operative which means after surgery] recovery course due to bowel ileus [disruption of normal intestinal propulsive action]..."		*Non-radiopaque towels are only to be used for:* *1. The drying of hands after the surgical scrub* *2. As a drape for the surgical site under the sterile disposable drapes(necessary to use non-radiopaque towels in the event an x-ray is needed)* *3. Opened and placed on the surgical tables and mayo stands under sterile instruments.* *Any remaining non-radiopaque towels are removed from the sterile table and handed off to the circulating Registered Nurse (RN) to a location away from the operative area prior to incision. If the surgeon or assistant requests sterile towels for any purpose after surgery has begun, radiopaque towels will be provided. These towels are counted if the case meets the criteria for instrument counts per the facility policy titled "OR - Counts in the OR". The policy states: "Instruments need not be officially counted if a major body cavity has not been entered, or the depth or location of the wound is such that an instrument could not potentially be left in the patient."* *On July 10, 2014 a memo was sent from the Director to all surgical staff on the changes in the process for handling sterile towels. The surgical services leadership (Director, Manager, Supervisors and Charge Nurses) spoke to all individuals working in surgery that day regarding the process change.* *On July 10, 2014 the operating room (OR) staff began to verbally communicate the process change to the physicians immediately on a case by case basis with formal presentation to the surgical advisory committee on August 13, 2014.*	

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	The Operative Report from Hospital 1 (dictated by MD 1) and dated 4/8/14, indicated the pre-operative and post-operative diagnoses as muscle invasive bladder cancer, the procedures performed as radical cystoprostatectomy, bilateral lymph node dissection (removal of lymph tissue - specialized tissue to fight infections), placement of bilateral (both sides) single J ureteral stents via ureterotomy (placement of a hollow tube in the shape of the letter J inside the ureter during surgery to ensure drainage of urine from the kidney), and ileal conduit urinary diversion. The operative report by MD 1 further documented "...The patient was awakened from general anesthesia and taken to the recovery room in satisfactory condition..." The Intraoperative Record for the 4/8/14 surgery was reviewed and indicated on page 3 (of 8) that sponge, needles and sharps count was correct, but the scissor count was incorrect. The record indicated, "Scissor count incorrect, we had one more than the first count ..... x-ray ordered." On 7/25/14 at 11:58 a.m., during a concurrent record review and interview, the X-ray report for 4/8/14 was reviewed and indicated the x-ray was done due to an incorrect count in the OR. The report also indicated, "...no definite foreign body otherwise seen on these images. If there is a high clinical index of suspicion for a foreign body, a CT (computerized tomography - a specialized three dimensional x-ray) scan is suggested." MD 1 stated he did not order a follow up CT scan because the X-ray was done due to extra instruments being found during the count and he did not feel the CT scan was necessary.		*On July 11, 2014 Education was provided at the surgery staff meetings on the new count process for towels in the operating room. All staff required to review educational Power Point and sign attestation.* *On July 15, 2014 an audit of 100% of surgical cases meeting the criteria for the new count process for towels was initiated. The audit was conducted for four months (completed November 15, 2014) and will be continued as a random check twice a week to ensure ongoing adherence to the process.* **B. The title or position of the person responsible for the correction;** *The Director of Surgical Services is responsible for ensuring adherence to the new process for handling sterile towels in the operating room.* **C. Plan for continued compliance and description of the monitoring process to prevent recurrence of the deficiency;** *On July 15, 2014 a four month audit was initiated for 100% of cases meeting the criteria for instrument counts per the facility policy titled "OR - Counts in the OR". The policy states: "Instruments need not be officially counted if a major body cavity has not been entered, or the depth or location of the wound is such that an instrument could not potentially be left in the patient."*	

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	An OR nursing note for 4/8/14 indicated, "X-ray ordered for surgical instrument count, [MD 1] read the x-ray and confirmed that it was negative." On 9/29/14 at 11:37 a.m., during a concurrent clinical record review and interview, the report for the x-ray performed on 4/11/14 indicated, "Clinical History: Pain. NG [nasogastric - from the nose to the stomach] tube placement". The report also indicated, "Mild dilatation [enlargement] of the proximal small bowel loops for which developing small bowel obstruction cannot be fully excluded. Please correlate clinically and consider follow-up radiographs as indicated." The RM for Hospital 1, when asked if there was any follow-up done on the x-ray dated 4/11/14, stated, "The x-ray showed an ileus, which is not uncommon after this type of surgery, and no follow up was necessary." The clinical record indicated Patient 1 was discharged on 4/16/14 and the discharge summary documented the following "... Patient Instructions: Activity: No heavy lifting or strenuous activities; Diet: as tolerated; Wound Care: as directed; Follow-up: with (MD 1) in office for staple removal." On 7/21/14 at 11:16 a.m., during an interview, Patient 1 stated he had the first surgery done by MD 1, at Hospital 1, on 4/8/14. Patient 1 stated, "I was kept in the hospital a few extra days because my abdomen was swollen and I had some nausea and vomiting, but felt, 'Ok,' when I was discharged. Patient 1 stated, "My sense of feeling 'OK' lasted about a week and then I began to not feel good."		*The Registered Nurse circulator would complete an audit form on all surgical cases that met the criteria for instrument counts that included:* *• Non-radiopaque towels only utilized for drying hands, draping mayo, back table and patient.* *• All remaining non-radiopaque towels were removed from the field and passed off to the circulating nurse before incision.* *• If opened, were radiopaque towels counted as per policy?* *Surgical Services Manager, supervisors and charge nurses as well as Patient Safety staff did random checks for compliance with the process as well.* *The 100% audit was completed on November 15, 2014 with 100% compliance with the new process.* *Two random cases per week will continue to be audited for compliance.* *The results of the audit will be reported to the Quality Patient Safety Committee at the February 2015 meeting for Quality Assurance/Performance Improvement purposes.* **D. Date the immediate correction of the deficiency will be accomplished. Normally, this will be no more than thirty days (30) from the date of the exit conference.** *February 19, 2015*	02/19/2015

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	Patient 1 stated, "By 5/10/14 I had lost 43 pounds, my bowels were not working right, I had no energy, no stamina, and I felt like I might not live." Patient 1 stated, "I couldn't even drive myself to my doctor appointments during this time, and I could not even walk from the bed to the couch without becoming fatigued." Patient 1 stated, "I was so depressed, I never felt good anymore, and I had no quality of life, I just wanted my life back." Patient 1 stated he had a follow up appointment with MD 1 on 6/29/14 and informed MD 1 of his symptoms. Patient 1 stated he was given dietary instructions and MD 1 ordered laboratory samples, a CT scan of the abdomen, and a chest x-ray. Patient 1 stated, he had the CT scan done on 6/4/14 at Hospital 2. Patient 1 stated, "I had a follow up appointment with [MD 1] on 6/14/14 and found out I had an abdominal mass." Patient 1 stated, "This is when I was finally referred to [MD 3]." Patient 1 stated, "I was so scared when I was told about the abdominal mass because I knew something was wrong and thought I must be full of cancer." Patient 1 stated he had an appointment with MD 3 on 6/18/14 and was told by MD 3 he had a, "large abdominal mass and it was probably infected." Patient 1 confirmed he had the second surgery at Hospital 2 on 7/7/14, done by MD 3. Patient 1 stated, "After the surgery [MD 3] told me she found a towel inside me. I just can't believe this happened to me." The outpatient progress note for 6/12/14 (dictated by MD 3) indicated "... Reason for Appointment: Abd (abdominal) mass. History of Present Illness: Patient 1 ... Has not felt well for the last few months and has lost 50 pounds since March ... He			

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	has had pain in his right lower abdomen with anorexia [loss of appetite] and low grade nausea ...CT scan showed a large mass just lateral to his ileal conduit...General Examination: ...Very, thin, acutely ill [rapid onset] appearing male, with appearance of some chronic underlying problems ... abdomen: tenderness with ill-defined fullness RLQ [right lower quadrant - meaning the right lower side of the abdomen] lateral to ileal conduit ...anxious appearing, mood depressed ... Review of Systems: ..Patient complaining of change in appetite, fatigue, headache, weight loss ...abdominal pain, decreased appetite, nausea ...weakness ...loss of strength ...depressed mood-current illness starting to get to him." An Operative Report from Hospital 2, for 7/7/14 (dictated by MD 3) indicated, "Procedure: Exploratory laparotomy [A laparotomy is a large incision made into the abdomen. Exploratory laparotomy is used to visualize and examine the structures inside of the abdomen], opening of abscess [collection of pus] cavity, removal of foreign body [blue surgical towel]. Post-Op Diagnosis [DX]: retained foreign body [blue surgical towel]. Findings: abscess cavity ...purulence released upon opening abscess cavity ... The Narrative Summary indicated: There was a considerable amount of pus that drained immediately. Cultures [laboratory samples] were obtained. Once this drained we could see a blue surgical towel wadded up. This was teased from the cavity and was found to have purulent exudate (pus) and a few clots on it. Pictures were taken of the blue towel as we saw it after entering the cavity, the			

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	blue towel removed and abscess cavity emptied ..." (Photographs were included in the investigative evidence). A Surgical Pathology Report from Hospital 2, for 7/9/14 indicated, "Diagnosis: Abdomen: Blue cloth material, consistent with foreign body. Clinical History/Preoperative Diagnosis: ...Status post cystectomy, ileal conduit prostatectomy, abdominal mass vs. abscess. Postoperative Diagnosis: Same, blue towel foreign body removed from abdomen, surgery 4/2014 (Hospital 1). Gross Description: Received is a 46 x 34 cm [centimeter - approximately 19 inches by 14 inches] blue-colored fabric material with no attached soft tissue ..." On 7/22/14 at 9:18 a.m., during an interview, the Risk Manager (RM) for Hospital 1 stated a root cause analysis (RCA) was conducted immediately upon learning about the retained blue surgical towel. The RM stated, "During the RCA, we discovered the towels are not items that are counted in the OR during surgery, therefore the count would have appeared correct." The RM stated Patient 1 developed some post-op complications and an x-ray was done, "...But because the towel was not radiopaque (visible on x-ray), it was not seen at that time." The RM stated, "The accepted OR procedure when any item is placed in a body cavity during surgery is to shout it out and write it on the white board (a dry erase board used to keep track of any additional items used during surgery) in the OR." On 7/25/14 at 9:08 a.m., during a concurrent			

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	interview, the Director of Surgical Services (DSS) and the Manager of Surgical Services (MSS) stated, "The OR staff was, 'devastated' when they heard about the retained foreign body." The DSS stated, "Nobody in the OR present at the time of [Patient 1's] surgery recalled the towel going in." The DSS stated, "The towel was obviously overlooked because what goes in is supposed to come out, and that did not happen in this case." The DSS and MSS stated the blue towels have never been a countable item in the OR. The DSS and MSS also stated, "The blue surgical towels were only available for the surgeons to dry their hands after scrubbing in, or to drape on a patient, not to ever be used internally." The DSS and MSS stated, "This was a lesson learned, the blue surgical towels will no longer be allowed on the surgical field once an incision is made. Only radiopaque towels will be allowed. On 7/25/14 at 9:35 a.m., during an interview, Registered Nurse (RN) 1 stated she was the circulating nurse at the beginning of Patient 1's surgery. She stated there was a table set up behind the doctor and scrub nurse. The table contained sterile instruments, and blue surgical towels. RN 1 stated blue surgical towels were not countable items in the OR. When questioned about the hospital policy regarding that the circulating nurse should be aware of all items used during a surgery to prevent retained objects, RN 1 stated she was aware of that policy, but it would be possible for a surgeon to grab something off the table without anyone seeing it happen. RN 1 stated she was relieved by another nurse shortly after the			

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	surgery began and did not know if MD 1 or MD 4 (surgeon and assistant surgeon) took a towel off the table during Patient 1's surgery. On 7/25/14 at 10:12 a.m., during an interview, RN 2 stated she recalled seeing the blue surgical towels on the back table during Patient 1's surgery. She stated, "It is common for surgeons to use the blue surgical towels to cover organs during procedures, but I do not recall if that happened during this surgery." RN 2 stated the accepted procedure would be for the surgeon to inform the entire OR staff when a towel was used. For example, surgeon would say, "Blue towel in," and the circulating nurse would repeat, "Blue towel in," and write it on the white board. Then when the towel was removed, the surgeon would call out, "Blue towel out," the circulating nurse would repeat, "Blue towel out," and erase it off the white board. RN 2 stated she did not recall if any blue surgical towels had been used during Patient 1's surgery. On 7/25/14 at 10:18 a.m., during an interview, the Scrub Technician (ST) stated, she did not recall Patient 1's surgery. The ST stated the accepted procedure in the OR was that the surgeons would ask the ST to hand them needed items, not take items off the table themselves. The ST stated she was involved in cases where the surgeons did not follow this protocol, and have grabbed items themselves. ST stated she did not recall if that happened during Patient 1's surgery. The ST stated if an item was used during a surgery, it would be called out to the circulating nurse, written on the white board, and called out again when removed.			

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	The ST did not recall if that happened during Patient 1's surgery. When asked what the hospital's policy was regarding blue surgical towels in the OR, the ST stated, the towels were there for the surgeons to dry their hands. The ST stated the blue surgical towels were not considered part of the count; therefore the count would appear to be correct for Patient 1. On 7/25/14 at 11:58 a.m., during an interview, MD 1 stated he would normally use a blue surgical towel during a surgery when retracting the bowel. MD 1 stated if he did use a towel, he would call it out and the nurses would write it on the board. MD 1 stated he did not recall placing a towel in Patient 1's abdomen. When questioned about hospital policy that stated non- radiopaque towels (towels that are not visible upon x-ray) were to be used for draping only and not to be used within a body cavity or to retract viscera (the internal organs in the main cavities of the body, especially those in the abdomen - for example, the intestines), MD 1 stated, "In retrospect that makes sense. But, during surgery, you don't really think about that, it doesn't really click that towels are non- radiopaque. I normally don't stick the towels all the way in, I usually leave a corner sticking out so I can see it and remember it is there." MD 1 stated he looked in Patient 1's abdominal cavity before he closed the site, but he did not see the blue surgical towel. On 7/25/14 at 12:15 p.m., during an interview, MD 4 stated he was the assistant surgeon for MD 1 during Patient 1's surgery. MD 4 stated he recalled someone in the OR called out, "Blue towel going			

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	in." MD 4 could not recall who called it out, but stated he was sure it was called out. MD 4 stated the instrument count was incorrect at the end of Patient 1's surgery. The count showed there was an extra pair of scissors, so an x-ray was done to confirm nothing had been left in Patient 1's abdomen. MD 4 stated the x-ray was negative for a retained object, so Patient 1 was closed and the surgery was complete. MD 4 stated the blue surgical towels were not part of the surgical count. On 9/1/14 at 8:46 a.m., during an interview, MD 3 stated she saw Patient 1 before the exploratory laparotomy surgery. MD 3 stated Patient 1, "Looked acutely ill, was easily fatigued, had no energy for months, experienced an extreme weight loss, and was extremely depressed. He had a palpable mass in his abdomen that was also seen on CT scan. When we broke into the abscess cavity, pus immediately came out, then after the pus, you could visualize the blue towel crammed in there. I could certainly see how someone could put something in there to retract, because the towel was found right behind the ileal conduit." MD 3 stated she provided pictures taken during the surgery that showed the towel in the abdomen as they saw it, and also the large amount of pus and blood on the towel. On 11/10/14 at 3:40 p.m., during an interview, when questioned about the hospital's policy and procedure regarding countable items in the OR, the RM stated the blue surgical towels have never been a countable item. The RM stated that particular part of the policy and procedure "... pertains to items			

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(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
	that are added to the surgical field during surgery and the blue towels are not part of the count because the towels are well documented everywhere else and it has always been known by the surgical staff not to use those towels on a patient." The hospital's policy and procedure titled, "OR-Counts in the OR," dated 3/27/14, indicated, "...II. Countable item: Any surgical item that could be potentially be left inadvertently in the patient on the operative field or in the oropharynx. Countable items may include sponges, suture needles, hypodermic needles, blades, instruments, cautery tips, cautery cleaners, vessel loops, vessel clip bers, raney scalp clips, aneurysm clips, umbilical tape, throat packs, bite blocks, and others...:III. B. The RN circulator is to pro-actively oversee and participate in safety measures with the entire perioperative team, and observe the sterile field to prevent RSI's (retained surgical instruments) ...C ...The scrub person ... 2. Maintains an awareness of the location of all soft goods, instruments, and miscellaneous items on the sterile field during the operation ... D. The surgeon(s) and surgical assistant (s) are to maintain awareness of all soft goods, instruments and sharps used in the surgical wound during the course of the procedure. 1. Use only radiopaque items in the wound. 2. Communicate placement of surgical items in the wound to the perioperative team for notation ... H. Non-radiopaque sterile cloth towels are intended for draping only and must never be used within a body cavity to sponge, retract viscera, or pack a body cavity ..."			

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
	050060	A. BUILDING _____ B. WING _____	09/30/2014

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	The hospital failed to follow their OR counts procedure for the surgery of Patient 1 on 4/8/14. This failure directly led to a surgical OR towel being retained in Patient 1 for 3 months. The retained foreign object directly led to an additional hospitalization and an additional surgery on 7/7/14 to remove the retained foreign object. The hospital's failure resulted in preventable pain, emotional and psychological suffering, injury, and harm. The failure to develop and implement the hospital policy and procedure for OR counts directly led to the licensee's noncompliance with one or more requirements of licensure and caused or is likely to cause, serious injury or death to the patient. The hospital's failure may result in an Administrative Penalty. 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).			