The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number: CA00218897 - Substantiated

Representing the Department of Public Health: [Redacted], Health Facilities Eval. Nurse

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, injury or death to the patient.

Abbreviations and Glossary:

1. Abscess- A localized collection of inflamed tissues.
2. Circulator or circulating nurse- Registered nurse who is responsible for delivering quality nursing care to the patient in the OR using the nursing process. This RN makes preparations for an operation and continually monitors the patient and staff during its course, who works in the OR outside the sterile field in which the operation takes place, and who records the progress of the operation, accounts for sponges, instruments and specimens.
3. Counter bags- Transparent bags into which sponges are individually inserted by the circulating nurse.

The statements made on this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein.

This Plan of Correction constitutes UCSF Medical Center's written credible allegation of compliance for the deficiencies noted.

Corrective Action OR staff (RNs and Surgical Techs) were re-educated on the policy "Counts:

Instruments, Sponges, Needles and Small Items" during an in-service that took place on 2/24/10 and was repeated on 4/14/10. An additional in-service was held for Surgical Techs on 3/10/10. The education provided during these in-services covered the entire "Count" policy. It included information specific to the procedures around manual entries in the Surgicount system (e.g., requiring RN initials, documentation of the reason for the manual entry, and completion of an Incorrect Count Form). The
Continued From page 1

nurse, after they are counted.

4. CT scan- A sectional view of the body constructed by computed tomography.

5. Enteric- Relating to the intestines.

6. Exploratory laparotomy- Also "exploratory lap" or "ex lap". A surgical opening of the abdomen for exploration and examination of body organs and tissue.

7. Gross diagnosis- A determination or diagnosis made by using the naked eye instead of a microscope.

8. Laparotomy sponge- Also "lap sponge" or "lap tape". An absorbent pad constructed of gauze and cotton with an embedded radiopaque fiber used to absorb fluids and blood in surgery.

9. Omentum- A double fold of peritoneum (the membrane covering the abdominal organs and lining the abdominal cavity) attached to the stomach and connecting it with the abdominal organs.

10. OR- Operating room.

11. Radiopaque- An entity that is impenetrable to x-rays or other radiation.

12. Raytec- A brand name for a 4x4 or 4x8 gauze sponge with an embedded radiopaque fiber. Also referred to as "raytex" sponges.

13. RN-Registered Nurse

14. Scrub- Refers to the surgical technician or RN who is responsible for directly maintaining the sterile field where the operation is taking place, and for delivering the sterile instruments, supplies and equipment directly to the surgical team.

15. ST- Surgical technician or surgical technologist. The unlicensed member of the surgical team. See #14, "scrub".

education reiterated the requirement that the manual scan out process should only be used if a sponge is damaged and cannot be read by the scanner; a manual entry should never be made if the sponge has not been located. The education also included policy requirements around the verbal confirmation of an accurate count with the surgeon (e.g. confirmation should not take place until all sponges are placed in the clear hanging bag). In addition to the all-staff education, the staff involved with the event were individually re-educated on the policy requirements. The performance of the circulating RN was monitored following this re-education to confirm compliance with the policy. All RNs and Surgical Techs in the OR are required to complete an annual competency on the count procedure. This competency has been revised to include a requirement for a 2 person (circulator and scrub) check of the correct sponge number before any manual entry into the Surgicount.

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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 disposable 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 disposable 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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16. Surgicount Safety Sponge System- A computer assisted surgical sponge counting system using bar coded surgical sponges and a hand held scanner.

17. Thrombosis-The formation, development, or existence of a blood clot or thrombus within the vascular (blood vessel) system.

**Title 22 70213(a)(b) Nursing Service Policies and Procedures**

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.

These Regulations were not met as evidenced by:

Based on interview and record review, the operating room staff failed to follow the hospital “Counts: Instruments, Sponges, Needles and Small Items” policy and procedure, as outlined in the “Perioperative Procedural Manual”. This policy failure resulted in the retention of a laparotomy sponge in the pelvic cavity of Patient 1.

**Findings:**

Patient 1 was transferred to the hospital on **9/10**

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**LABORATORY DIRECTOR’S OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE**

**TITLE**

**DATE**

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from another northern California hospital for medical and surgical management and intervention for gastric cancer. According to a review of clinical record on 6/21/10, Patient 1 was taken to the operating room on 2/10 and underwent an exploratory laparotomy and small bowel resection. Following the surgery, the patient demonstrated no clinical improvement and continued to sustain an elevated white blood cell count during postoperative period. Also continued to complain of abdominal pain. On 3/10 at 1:15 p.m. the patient had a CT scan of abdomen and pelvis. Among other significant clinical findings, including a complete thrombosis of the superior mesenteric artery was the following: "In the mid pelvis there is a 12x8 cm air-fluid collection containing mixed bubbly gas and soft tissue with hyperdense stripe consistent with a retained sponge."

The decision was made to return to the operating room on that same day for another exploratory laparotomy, removal of the foreign body, and abdominal wash out. The 3/10 operative report indicated: "Entry into the abdomen revealed approximately a liter of enteric fluid. There was an abscess in the pelvis and in the lower abdomen. On removal of the omentum, a foreign body was noted, which was removed and reported to the nursing manager." The 2/13 pathologic report noted: "The specimen is received in two parts, each labeled with the patient's name and medical record number. Part A, received fresh and additionally labeled 'small bowel' consists of two un-oriented small bowel segments with stapled margin. Part B is

Plan for continued monitoring will be reviewed by Perioperative Leadership.

**Responsible Party:** Director of Perioperative Services, Chief Nursing Officer

**Corrective Action** OR staff (RNs and Surgical Techs) were re-educated on the policy "Counts: Instruments, Sponges, Needles and Small Items" during an in-service that took place on 2/24/10 and was repeated on 4/14/10. An additional in-service was held for Surgical Techs on 3/10/10. The education provided during these in-services covered the entire "Count" policy. It included information specific to the procedures around manual entries in the Surgicount system (e.g., requiring RN initials, documentation of the reason for the manual entry, and completion of an Incorrect Count Form). The education reiterated the requirement that the manual scan out process should only be used if a sponge is damaged and cannot be read by the scanner; a manual entry should never be made if the...
received fresh and additionally labeled 'retained sponge, foreign body', and consists of a single, un-oriented, 25x25x0.4 cm blood tinged sponge cloth with a thin fabric mesh. This part is for gross diagnosis only."

On 6/2/10, the hospital "Counts: Instruments, Sponges, Needles and Small Items" policy and procedure was reviewed. The procedure to be followed included the following:

**Breaks/Lunch Relief and Permanent Relief**

"All incoming personnel must be present and participate in change of shift counts. The incoming staff will do the counts while the outgoing team will continue the procedure."

**Discarding Sponges From the Sterile Field**

1. "Sponges will be discarded in a ring stand basin/bucket.
2. Scanners and hanging sponge counter bag systems are used for all cases requiring a sponge count.
3. Sponges are scanned out and placed in the counter bags on an ongoing basis throughout the case. Do not allow sponges to accumulate in the ring stand basin/bucket.
4. The circulating nurse will separate the raytex and laparotomy sponges before placing them in the appropriate sponge bag counter pocket with the radiopaque indicator visible.
5. When a sponge counter bag is filled with 10 laps of 10 Cratex, the scrub and circulator together will verbally, audibly and simultaneously count them before putting an empty bag in front of a filled one."

The education also included policy requirements around the verbal confirmation of an accurate count with the surgeon (e.g. confirmation should not take place until all sponges are placed in the clear hanging bag). In addition to the all-staff education, the staff involved with the event were individually re-educated on the policy requirements. The performance of the circulating RN was monitored following this re-education to confirm compliance with the policy. All RNs and Surgical Techs in the OR are required to complete an annual competency on the count procedure. This competency has been revised to include a requirement for a 2 person (circulator and scrub) check of the correct sponge number before any manual entry into the Surgicount scanner.

**Monitoring:** Compliance with the policy "Counts: Instruments, Sponges, Needles and Small Items," specifically, the use of the Surgicount system, is being monitored through monthly audits.

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BAR-CODED ASSISTED COUNTING

"The SurgiCount Safety Sponge system is utilized on all surgical cases requiring a sponge count. All counted sponges will also be counted both manually and electronically by the scrub and by the circulator."

**Initial Count Out**
1. "Mount the scanner on the IV pole in the holster. Change screen to count out screen by tapping the "count out" box to activate the constant scanning mode. Don unsterile gloves and personal protective equipment.
2. Scan all discarded sponges from the sterile field as soon as possible separating and scanning the data matrix tags individually.
3. Place sponges in the hanging counter bag."

**Final Count Out**
1. "Follow the same sequence as initial count out."
2. Two sponges may be kept on the sterile field for patient cleanup during the final manual count. Sponges kept on the sterile field after final manual count must be scanned by either the circulator or scrub and placed in the hanging counter bag prior to the patient leaving the room.
3. Do not confirm final until all sponges are off the sterile field, scanned and in the hanging counter bag.
4. Confirm correct count when manual final count, written count and electronic count are identical.
5. Initiate corrective actions as stated in count policy."
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"If the scanner manual entry function is used for any sponge, document the reason on a Report of Incorrect Count form and document the scanner issue and the scanner number."

"At a permanent change of relief, the number of sponges in the ‘closed’ counters are physically reviewed using visual and audible communication between the circulating nurses changing positions before the relieved nurse departs the OR."

A 6/2/10 review of the Surgicount Scanner report dated 6/10, "Start Time: 08:11:16" revealed that all items had not been confirmed with a manual count, and that one 18x18 lap sponge, labeled "B49Z49", had been manually counted at 11:31:47, which was indicated by a "*" next to the time. Under the "Notes" section of the report, timed 11:31:55, was the notation: "Please explain reason for manually counting Items:" The section was left blank.

According to an interview with the hospital regulatory affairs RN on 6/10 at 1:25 p.m., the operating room had been using the Surgicount System since 3/07 and the OR staff were very familiar with its use.

During an interview at 1:35 p.m. on the same date, RN 1 told surveyors that she had done the first count with ST 1. She explained that the technician holds the sponges, which are individually barcoded, under the scanning device, which is held by the circulating nurse. She said she remembers scanning 18x18 lap sponges on the day of Patient
Continued From page 7

1's first surgery, but did not recall seeing 25x25 sponges in the operating room.

She stated, "Around 10:55 a.m. I knew I was due for a lunch break at 11 a.m. and was doing/getting ready to count with ST 1. We were missing one, because we had 39 sponges. I told Surgeon 1 we needed to look for it. There was a lap sponge on the floor in between the steps (step up lifts that are placed one on top of another to allow all team members, no matter what their height, to be the same height as the surgeon and the surgical field). We counted again and the count was correct. They were using the stapler (surgical staple device used to close the skin incision). In the meantime, RN 2 came in to relieve me for lunch. The patient was incontinent of bowel and we had to clean her up. You're supposed to bag (in the individual counter bags) all the sponges. I did not bag them. I missed the bagging. I should have been more assertive. When we count, give me time, that's the lesson I learned. I felt I was rushed in that situation."

In another interview on the same date at 2:10 p.m., RN 2 told surveyors, "I went into the (OR) room to give a lunch break. The patient was ready to transfer to the recovery bed. I didn't actually see if the sponges were in the bags, the patient was incontinent (of bowel) and we had to clean her up. RN 1 told me the sponges were counted, that the counts were all done." RN 2 added that the largest lap sponge in the OR was 18x18. "We don't have any 25x25 sponges."

In another interview on the same date at 2:12 p.m.,
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

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NAME OF PROVIDER OR SUPPLIER
UCSF MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
505 PARNASSUS AVENUE, SAN FRANCISCO, CA 94143 SAN FRANCISCO COUNTY

ID SUMMARY STATEMENT OF DEFICIENCIES
PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL
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ST 1 told surveyors, "At the end of the procedure, 5 sponges were not in the pouches (individual counter bags): 1 that fell to the floor during the case, 2 on the (surgical) field for clean up, and the two surgeons each had 1 in their hands. RN 1 came over to the field and scanned out everything, the 1 (lap) on the floor, the 2 I had, and the 2 the physicians had. The room was chaotic. RN 2 came in to relieve. The patient was incontinent (of bowel) and [ ] was waking up. There was pressure to turn over the room." Surveyors asked ST 1 if they had any problems with intimidation by the surgeon, in terms of the count process. She answered, "Surgeon 1 is very easy to work with. He's one of my favorites"

During an interview on 6/21/10, at 2:45 p.m. the Medical Director of Perioperative Services told surveyors, "I believe we know what happened here. RN 1 did not scan one of the sponges, maybe the one that fell to the floor. The scanner record proves it. If she had scanned it, the machine would have let her know that one lap was still missing. The staff weren't even particularly rushed. There wasn't another case in that room for another hour and a half. There was no pressure from the surgeon either. He is very amiable and cooperative with the staff. The lap sponge had been manually entered during the case. When she saw the sponge on the floor, she assumed it was the missing one. The lap sponge that was removed from Patient 1 was the one that RN 1 had manually entered. Since we started using the scanner, we have used 5 million sponges in the medical center and only lost one. The system works if the policy is followed."


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The Medical Director added, "There are no 25x25 lap sponges used in the OR. The pathology report was a measuring error."

RN 1 failed to follow the operating room counts policy by:
1. Manually entering an 18x18 lap sponge in the scanner during Patient 1's 29/10 surgery without documenting a reason for the manual entry on a Report of Incorrect Count form.
2. Not inserting each counted off sponge into the counter bag.
3. Not physically reviewing the number of sponges in the "closed" counters, using visual and audible communication, with R.N. 2, who had come into the room to relieve her for lunch.
RN 1 also failed to act as an advocate for Patient 1 by not assertively communicating with the surgeons that the final count was not yet completed, per #3 and #4 of the Final Count Out procedure. These failures resulted in the retention of a foreign body in a seriously ill, medically and surgically compromised patient.

The hospital's failure to ensure that the OR staff followed the surgical counts policy 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
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH  
SEP 15 2010  
L & C DIVISION  
DALY CITY

Event ID:UNOV11  
8/26/2010 12:49:28PM

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