The following reflects the findings of the Department of Public Health during a Complaint visit:

Complaint Intake Number: CA00173807 - Unvalidated

The inspection was limited to the specific facility adverse event investigated and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

[Signature]

RN-HJEN

1280.1(c) Health & Safety Code Section 1280
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 likely to cause, serious injury or death to the patient.

Deficiency Constituting Immediate Jeopardy

T22 DIV5 CH1 ART3-702223(c)(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.

THE PLAN OF CORRECTION IS PREPARED IN COMPLIANCE WITH FEDERAL REGULATIONS AND IS INTENDED AS COAST PLAZA DOCTORS HOSPITAL'S EVIDENTIARY EVIDENCE OF COMPLIANCE. THE SUBMISSION OF THE PLAN OF CORRECTION IS NOT AN ADMISSION BY THE FACILITY.

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How the correction will be accomplished, both temporarily and permanently:

1. The Operating Room Manager counseled the circulating nurse on 12/20/08 (Attachment A). Hospital Leadership suspended the circulating nurse indefinitely on 12/20/08 pending further investigation (Attachment B).

2. The Operating Room Manager counseled the scrub technician on 12/23/08 (Attachment C). He subsequently resigned his employment.

3. On 12/30/08, the Operating Room Manager in-serviced the Operating Room (Attachment D) staff on the "Sponge, Sharp, Instrument Count" (Attachment E) policy.
This RULE is not met as evidenced by:

Based on observation, review of facility documents, a review of Patient 1's clinical records and interviews with staff, the facility failed to ensure the Sponge, Sharp and Instrument Count policy and procedure were implemented. This policy/procedure failure resulted in the retention of two hemostats (surgical clamps for constricting blood vessels) in patient's abdomen and subsequently subjecting Patient 1 for potential for injury as a result of a retained foreign body and the necessity of undergoing a second surgical procedure for the removal of the retained surgical instruments.

Findings:

On January 27, 2008, a self reported incident was investigated regarding retained hemostats in Patient 1's abdomen.

The clinical record for Patient 1's initial admission was reviewed on January 27, 2008. The History and Physical dated December 5, 2008, documented Patient 1 presented to the emergency room (ER) for abdominal pain on December 5, 2008. The Operative Report, dated December 5, 2008, indicated the patient had a perforated colon and had a subtotal colectomy (excision of a portion of the colon), appendectomy (excision of the appendix), splenectomy (excision of the spleen), and hepatic colon colostomy (surgical creation of an opening between the colon and the body surface).

A review of the Intraoperative Record dated December 5, 2008, indicated the instrument count was correct. The Discharge Summary indicated the patient was discharged home on 01/30/09.

4. The Hospital revised its "Sponge, Needle, and Instrument Count" policy on 01/10/09. This policy was approved at the Medical Executive Committee (MEC) and the Board of Trustees on 02/10/09 (Attachment F).

5. On 02/11/09, the Operating Room Manager in-serviced the Operating Room staff on the revised "Sponge, Sharp, Instrument Count" policy, and the role of the circulating nurse during the surgery (Attachment G).

6. Staff participation in the OR was temporarily suspended. The Hospital developed a "Students in the Operating Room" policy that details the Hospital and student's responsibilities in the Operating Room. This policy was approved by the 02/10/09 MEC and the Board of Trustees (Attachment H).

7. On 02/11/09, the Operating Room Manager in-serviced the Operating Room staff on the "Students in the Operating Room" policy (Attachment I).

8. The Hospital and Medical Staff Leadership met with the surgeons on 01/28/09 to discuss the case.
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December 18, 2008.

The clinical record for Patient 1's readmission was reviewed on January 27, 2008. The history and physical, dated December 22, 2008, revealed that Patient 1 presented to the Emergency Room with abdominal pain and possible intestinal infections on December 22, 2008.

A review of the Radiology Report (abdominal x-ray) dated December 24, 2008, disclosed two views of Patient 1's abdomen. The first report (abdominal x-ray) disclosed, "two metallic hemoatlas type structures overlapping one another in the mid abdomen." The report indicated, "Findings suspicious for retained surgical instruments x 2 in the mid abdomen." The report also documented postoperative changes of the abdomen and possible small bowel obstruction. The second report (CT Abdomen and CT pelvis) indicated, "Retained surgical instruments in the mid abdomen with the appearance of two hemoatlas overlapping one on another." The report also documented small bowel obstructive pattern.

A review of the Operative Report, dated December 24, 2008, indicated a pre-operative diagnosis of small bowel obstruction and the presence of two hemoatlas (clamps) foreign body in the abdominal cavity region. The postoperative diagnosis indicated volvulus (tortion of a loop of intestine, causing obstruction) of small bowel and the presence of two hemoatlas not related to the obstruction. The report disclosed the patient had resection of small bowel volvulus, side-to-side anastomosis (surgical formation of a communication between two formerly distant portion of the intestines) and removal of hemoatlas.

The title or position of the person(s) responsible for the correction:

Operating Room Manager
Chief Nursing Officer
Chief of Staff
Medical Director
Chief Administrative Officer

A description of the monitoring process to prevent recurrence of the deficiency:

1. The Operating Room Manager has developed specific performance improvement indicators to monitor the accuracy of the "Sponge, Needle, and Instrument Count" and monitor the Operating Room staff's compliance with the policy (Attachment J). The results will be monitored by the Operating Room Manager and corrective action will be taken as needed. The results of the monitoring will be reported to the Quality Management Committee on a monthly basis. The Quality Management Committee will report on compliance to the Department of Surgery Committee on a quarterly basis. The Department of Surgery Committee will report on compliance to the MEC on a quarterly basis. The MEC will report on compliance to the Board of Trustees on a quarterly basis.
During an interview with Staff A on January 27, 2008 at 11:05 a.m., she stated the facility had not completed the investigation and there was no written action plan “at this time.” Staff A stated the facility had 45 days to complete the investigation.

During an interview with Staff B on January 27, 2009 at 11:30 a.m., she stated the retained instrument was a peel pack (additional instrument and was not part of the surgical tray). Staff B stated the instrument count was correct based on the instrument count list from the “major” tray. Staff B stated the instruments in the peel pack had a purple mark.

On January 27, 2009 at 12:40 p.m., during a tour of the operating room with Staff B, a white dry erase board with non-erasable pre-written countable items was observed on the wall of operating room suite.

During an interview with Staff B on January 27, 2009 at 12:50 p.m., she stated the instrument tray comes with an instrument list. Staff B stated the surgical tech and circulating nurse would count together audibly and visualize each item as it was counted. Staff B stated that additional instruments would be added to the base count and demonstrated how the additional item would be counted. Staff B proceeded to write on the white board, plus (4) 2 extra on the pre-written item of instruments. Staff B stated operating room staff may bring extra unopened peel packs and sutures, and place them on the circulating nurse table.

A review of a staff In-Service training session on Patient Safety (Sponges, Sharps, Instrument Count), dated December 30, 2008, was reviewed.

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2. The circulating nurse will be placed on three (3) months probation upon her return. The Operating Room Manager will observe the nurse for compliance with all policies and procedures as well as for technique/competency during the three (3) month period. The Operating Room Manager will review the nurses' performance with the Chief Nursing Officer and the Human Resources Director for any further action needed.
on January 27, 2009. The In-Service training indicated counts were performed to account for all items and lessen the potential for injury to the patient as a result of retained foreign body. The In-Service documentation indicated counts should be performed before the procedure to establish a baseline, before closure of cavity, within a cavity, before wound closure begins, at skin closure or at the end of procedure and at the time of a relief or either the scrub person or circulating nurse. The documentation further indicated that, "When additional instruments are added to the field they should be counted and added and recorded on the count board."

During an interview with Staff E on January 30, 2009 at 2 p.m., she stated that on December 5, 2008, she was called for an emergency case. Staff E stated the scrub tech prepared the room, prepared the major tray, basic pack and major basin. Staff E stated the major tray had an instrument list signed off by central processing as complete and she and the scrub tech counted the instruments together then taped the list to the white board. Staff E stated an additional unopened clamp peel pack was on the back table. Staff E stated she did not open any additional packs. Staff E stated the surgeon came with four medical students. Staff E stated two students assisted the surgeon and two students observed the procedure.

During the same interview, on January 30, 2009, Staff E reviewed the Intraoperative Record, dated December 5, 2008, and stated she did not write down the medical students' names. Staff E stated "My mistake." Staff E stated the case started at 1:15 p.m. and ended at 4:30 p.m., and that the surgeon performed four (4) procedures on one patient. Staff E stated she was in and out of the room to get warm normal saline solutions.
and sutures. Staff E stated the first count, which was before closing the peritoneum, was correct, the second count, which was before closing the fascia, was correct and the third count, which was before closing the skin, was correct. Staff E stated she wrote complete on the instrument list. Staff E stated she went with the patient to the Intensive Care Unit (ICU) and, upon her return to the OR, someone was in the process of cleaning the room.

Staff E stated, "The instruments, 2 paons (clamps) that were left behind (inside of Patient 1’s abdomen) were peel packs" Staff E stated, "I did not open peel pack. I don’t know who opened it." Staff E stated, "I was the only nurse in the room." Staff E stated every time an additional instrument was opened during the surgical procedure on Patient 1, the scrub tech and circulating nurse would count together then the circulating nurse would write the count on the board. Staff E stated students were told not to open anything. Staff E stated the policy and procedure stipulated the following: The circulating nurse must open peel pack, count with scrub tech and write additional instrument on the board. Staff E stated, "The peel pack instrument was marked. Staff E stated it was not counted, nobody informed me."

A review of The Recommended Practices for Sponge, Sharp and Instrument Counts (Association of Perioperative Registered Nurses - AORN 2007 Standards, Recommended Practices, and Guidelines) provided by the facility indicated that, "When additional instruments are added to the field, they should be counted and recorded as part of the count documentation."

The facility policy and procedure titled "Sponge, Needle and Instrument Count" (Item No. 7420..."
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059) dated August 2004, stipulated that instruments should be counted on all procedures in which the likelihood exists that an instrument could be retained and also for inventory control.

This policy and procedure failure resulted in a preventable foreign body retention for Patient 1 and subjected the patient to undergo a second abdominal surgical procedure, including the use of general anesthesia, for the removal of the retained surgical instruments.