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

Complaint Intake Number:
CA00242778 - Substantiated

Representing the Department of Public Health:
Surveyor ID #22779, 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.

Health and Safety Code 1279.1. (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 1279.1(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.

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.
Continued From page 1

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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

T22 DIV5 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 regulation is NOT MET as evidenced by:

Based on interview and record review, the hospital failed to ensure implementation of its written policy and procedure and current standards of practice in that it did not perform a thorough follow-up after a surgical count identified a surgical sponge was missing with the result that a sponge was retained for two and one half months with delayed wound healing and the increased risk of infection.

Findings:

On 9/7/10, the hospital notified the Department of a

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Laboratory Director's or Provider/Supplier Representative's Signature: [Signature]

Title: [Title]

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Continued From page 2

retained foreign object in a patient. The hospital reported that Patient A, while in the physician's office on 1/2010 for a post-surgical visit complained of irritation at a right axilla (armpit) incision site. The physician examined the area and found a sponge protruding from the wound (a sponge is defined as a gauze pad used to absorb fluids, protect tissue, and/or apply pressure or traction). The patient had surgery in this area on 1/2010 at the hospital.

Review of the hospital's Policy and Procedure, "Count: Sponge, Sharp and Instrument," revised 1/2010, showed counts would be counted before the procedure to establish a baseline, before closure of a cavity within a cavity, before wound closure, and before skin closure or the end of the procedure. The Policy and Procedure also showed when a discrepancy in counts was identified the surgical team's actions would include a manual check of the surgical site. The hospital's P& P for surgical counts cited, as a reference, AORN (Association of Perioperative Registered Nurses) Standards and Recommended Practices 2008.

On 9/27/10, a review of Patient A's medical record showed, on the preoperative assessment form dated 9/27/10, the patient's weight was listed on the assessment form under special circumstances. The patient was obese. A review of Patient A's operative report showed the patient had bilateral mastectomies and breast reconstruction with insertion of tissue expanders on 10/10. The surgery consisted of two stages with two different physicians, MD 1 and MD 2. The first stage of the surgery was performed on 10/10.

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b) The title or position of the person responsible for correction
Director of Surgical Services

c) A description of the monitoring process to prevent recurrence of the deficiency.
Each two procedure case will be monitored at 100% for the next 3 days.
continued from page 3

surgery was performed by MD 1 and was a bilateral mastectomy (removal of the breasts) and axillary lymph node dissection (the axillary lymph nodes are located under the arm). Axillary lymph node dissection is performed to determine if cancer has spread beyond the breasts. MD 2 performed breast reconstructive surgery as the second part of the patient's surgery.

On 9/27/10 at 1515 hours ST 1 (Scrub Technician) was interviewed. ST 1 stated she wasn't present for the first stage of the surgery done by MD 1 but joined the surgical team during MD 2's stage of the surgery. According to ST 1, when the second count was done, prior to MD 2's closure of the surgical site, one raytec sponge was missing. ST 1 stated she told MD 2 a raytec sponge was missing and MD 2 replied he did not use raytec sponges. A thorough search of the OR (operating room) suite was conducted; however, the sponge was not found. MD 2 ordered an x-ray to determine if a foreign body was in the patient. The radiologist report, reviewed on 9/27/10, showed a chest x-ray was done at 1715 hours and there was no foreign object seen.

On 9/27/10 at 1550 hours RN 1 (the circulating nurse) was interviewed. According to RN 1, after MD 1 finished the first part of the surgery, MD 2 took over using a separate set of instruments. There was no count done after MD 1 was finished with the first part of the surgery. After the count discrepancy was noted, and MD 2 was informed, a chest x-ray was performed. According to RN 1, MD 2 did not review the chest x-ray, and instead, the...
Continued From page 4

results were read to the ST 1 over the phone. A subsequent review of the chest x-ray showed that the x-ray did not extend to the patient's axillary area.

On 9/27/10, the Director of Clinical Excellence stated MD 1, when interviewed about the event, did not remember being notified of a count discrepancy.

On 9/27/10, a review of MD 1's operative procedure showed an incision was made in the axilla and three lymph nodes were removed and sent for testing. There was no mention if this incision was closed by MD 1.

On 9/27/10, a review of MD 2's operative procedure report showed no mention of closure of the axillary incision and no documentation of an incorrect count.

On 10/1/10 at 1100 hours during a telephone interview, MD 2 stated that, although not sure, he almost positively believed MD 1 closed the axillary incision prior to the start of the second stage of surgery as that was the usual practice. MD 2 also stated that the actual chest x-ray was not reviewed and that he was not aware if MD 1 was notified of the sponge count discrepancy.

The hospital's failure to ensure implementation of its policies and procedures for a surgical count of sponges, instruments, and sharps prior to closure of the axillary incision of Patient A, and for a manual search of the surgical site, including the

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Continued From page 5

Axillary surgical incision, after a count identified a surgical sponge was missing, 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(c).

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).