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
	050454	A. BUILDING _____ B. WING _____	09/09/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UCSF MEDICAL CENTER	505 PARNASSUS AVENUE, SAN FRANCISCO, CA 94122-0210 SAN FRANCISCO COUNTY

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	The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit: Complaint Intake Number: CA00160164 - Substantiated Representing the Department of Public Health: [redacted], 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. 70213(a) Nursing Service Policies and Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. 70213(b) Nursing Service Policies and Procedures (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.		**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:** UCSF Medical Center has provided extensive education to all surgical staff on the requirements of the UCSF Medical Center policy and procedure *Counts: Instruments, Sponges, Needles and Small Items*. Neurosurgeons and residents were reminded that whenever a retained foreign body is suspected, an x-ray is required by hospital policy. A Patient Safety Quality Bulletin was distributed to all staff on October 10, 2008. In addition to reinforcing the *Count* policy, a total of seven in-services were provided beginning in September of 2008 to all surgical staff involved with the count process. The in-services included training on assertive communication. Highly	9/17/08 10/10/08 9/2008 to 4/2009

Event ID: SSKO11 5/11/2010 8:29:43AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Helene Carnazey TITLE: Director, Regulatory Affairs (X6) DATE: 5/27/10

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6/25/10

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	Continued From page 1 70223 (b)(2) Surgical Service General (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. These Regulations were not met as evidenced by: Based on interview and record review, the surgeon and the scrub nurse failed to implement the facility's Policy and Procedure on Counts: Instruments, Sponges, Needles and Small Items, when a drill bit was noted to be missing during Patient 1's surgery to remove a brain tumor. The scrub nurse failed to advocate for the safety and positive surgical outcome for Patient 1 when she failed to obtain an x-ray prior to the patient leaving the operating room. These failures resulted in a drill bit being left in Patient 1 who had to undergo a second surgical procedure to remove the retained foreign body. Findings: Patient 1 was admitted to the hospital from an outside facility on 5/15/08 for evaluation and		Reliable Surgical Team (HRST) training was provided to all staff involved with the count process (RNs, Surgical Techs, Physicians, etc.). Over one thousand employees were trained between September of 2008 and April of 2009. HRST training is a four hour session provided by an interdisciplinary training team and focuses on surgical team communication. It aims to empower nursing and other staff to speak up if they believe there is an issue with patient care, such as the need to get an x-ray to confirm an incorrect count. The training also focuses on teaching team members to listen when other members of the team raise a concern. HRST training teaches nursing staff to advocate on the behalf of patients when they have a concern with patient care. **Monitoring**: October of 2008-2009, approximately 50 cases per month were observed to ensure compliance with the count procedure. Results showed 100% compliance with the policy. Whenever the count is incorrect, an incorrect count form is completed. All incomplete count forms are reviewed by the Patient Care Manager of the operating room	10/2008

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	Continued From page 2 treatment of a left parietal lobe mass (brain tumor). On 5/19/08, the patient had surgery to remove the tumor. A post operative head CT (computerizad x-ray generating a two dimansional image) on 5/21/08 showed a retained metal foreign object. Patient 1 was readmitted to the facility on 7/21/08 and had a second surgery to remove a retained drill bit. During an interview on 8/15/08 at 12:25 p.m., the Licensure and Certification Coordinator stated that Surgeon 1 and RN 1 failed to follow the facility's Counts: Instruments, Sponges, Needles and Small Items policy and procedure. She stated they were aware that the drill bit was missing prior to the patient leaving the operating room but failed to obtain an x-ray as required by the policy and procedure. She said she learned about the incident last week and reported it to CDPH (California Department of Public Health) on 8/13/08. She stated "I know we are late in reporting it." On 8/15/08 at 1 p.m., Patient 1's Intraoperative record dated 5/19/08 was reviewed and showed that the preoperative and final sponge, needle and small items count were documented as correct. There was a post operative MRI (magnetic resonance imaging) dated 5/20/08 which indicated the following: " A large signal void is present over the left frontal lobe as a result of metallic artifact arising from a retained drill bit in the left frontal bone, that is identified on the		to ensure that an x-ray was taken at the time the incorrect count was detected. Beginning Jan 2010, an ongoing process for monitoring compliance was initiated in which approximately five cases per week are observed for compliance with the count procedure. Results are reviewed by the Patient Care Director for Perioperative Services. Discrepancies are acted upon immediately and staff education is provided when necessary. In the event of a suspected unintended retained foreign body, an incident report is generated and reviewed by clinical staff to determine if further investigation is needed. Serious events, such as confirmed retained foreign bodies, are reviewed by UCSF Medical Center's Patient Safety Committee, which meets weekly, where the plan for responsive action is determined. **Responsible Party**: Chief Medical Officer, Director of Perioperative Services	1/2010

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	Continued From page 3 CT performed subsequently on 5/21/08. This artifact almost completely obscures the underlying surgical bed." Patient 1's operative report dated 7/21/08 indicated a pre and post operative diagnosis of left retained drill bit. The operation was listed as "Reopening of anterior cranial wound to remove retained drill bit." The description of the procedure included the following: "We removed the plate that was covering the anterior bur hole and saw underneath the plate a tack-up hole and a few millimeters below the surface in the tack up hole was what appeared to be a foreign body. We used a mosquito clamp to grab onto the end and pulled it out without any bleeding coming through the hole. When we were done, the retained drill bit was then sent to Pathology ....." The facility's Counts: Instruments, Sponges, Needles and Small Items policy and procedure indicated the following: II. Purpose To provide quality care and ensure maximum patient safety against accidental sponge, sharps, instrument and/or foreign body retention within the body during surgical intervention. Reasons for counting include: To prevent retention of inadvertent foreign body To reconcile with the baseline count To honor the request of any surgical team member to reconcile discrepancy or doubt.		State of California CDPH – L&C JUN 01 2010 Daly City Dist. Offic	

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	Continued From page 4 III. Procedure A. All counts 7. An X-ray is mandatory, prior to leaving the OR on cases where: c. Count discrepancy exists (see section IV. A Incorrect Counts) 10. Items broken during a procedure are accounted for in their entirety as documented on the count sheet. IV. Troubleshooting A. Incorrect Counts 1. Any discrepancy is treated as an incorrect count. B. When a discrepancy cannot be reconciled, an X-ray is MANDATORY before the patient leaves the room. On 9/9/8 at 09:05 a.m., Surgeon 1 was interviewed and stated he had used a "tack up "drill during Patient 1's surgery. He said that ST 1 (surgical technician) had noticed that the tip of the drill bit was broken and had brought it to his attention. He stated he inspected the wound twice but was unable to locate the missing drill bit. He said "It's my responsibility, I should have asked for an x-ray." RN 1 was interviewed on 9/9/08 at 09:35 a.m. and stated she was the relief circulating and scrub nurse for Patient 1's surgery. She stated she was the scrub nurse while ST 1 was at lunch. She said Surgeon 1 handed her the drill			

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	Continued From page 5 which she put in a basin in case it was needed again. RN 1 stated that when ST 1 returned, she went to lunch and later gave a break to the circulating nurse. She said that prior to the end of Patient 1's surgery, ST 1's shift ended so she (RN 1) relieved her. She stated that ST 1 noticed the drill bit was broken and notified her and Surgeon 1. She stated that she and ST 1 searched for the drill bit but were unable to find it. She said "(name of ST 1) suggested an x ray before she left." When asked if an x ray was obtained, RN 1 responded "No." She stated that Surgeon 1 had asked her "Should we take an x ray" but she had responded "I don't think so." She said "My assumption was it (the drill bit) was in the suction canister." She acknowledged that she failed to follow the facility's count policy and procedure and failed to act as an advocate for Patient 1 when she did not obtain an x ray despite being aware of the missing drill bit. During an interview on 9/9/08 at 10:40 a.m., ST 1 stated she noticed that a piece of the drill bit had broken off prior to the closure of Patient 1's incision. She said she searched the Mayo stand but was unable to find the drill bit. She stated she notified Surgeon 1 and RN 1 that the drill bit was missing. ST 1 said that her shift finished before the end of Patient 1's surgery but that before she left she told Surgeon 1 and RN 1 "We haven't found it, we really should get an x ray." She said that Surgeon 1 responded "We will keep looking." ST 1 said "I thought			

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	Continued From page 6 they would get an x rey before the patient left the OR so we wouldn't have to go back in." Patient 1 had to undergo the risks of a second major surgery and general anesthesia to remove the retained drill bit. The facility's failure to ensure that Surgeon 1 and RN 1 implement its Policy and Procedure on Counts: Instruments, Sponges, Needles and Small Items and RN 1's failure to act as an advocate for Patient 1 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. 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(o).		State of California CDPH – L&C JUN 01 2010 Daly City Dist. Offic CALIFORNIA DEPARTMENT OF PUBLIC HEALTH L & C DIVISION DALY CITY	

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