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
	050075	A. BUILDING _____ B. WING _____	12/03/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Oakland/Richmond	280 W Macarthur Blvd, Oakland, CA 94611-5642 ALAMEDA COUNTY

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

Complaint Intake Number:
CA00243799 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 20340, Medical Consultant

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.

T22 DIV5 CH1 ART7-70701(a)(7) Governing Body
(a) The governing body shall:
(7) Require that the medical staff establish controls that are designed to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter.

For clarification, terms/definitions used in this

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JUN 15 2012

Licensing & Certification
East Bay District Office

Preparation and execution of this plan of correction does not constitute admission of agreement by Kaiser Foundation Hospital - Oakland/Richmond of the truth of facts alleged or conclusions set forth in this statement of deficiency.

All exhibits referenced in the Plan of Correction are available on site at the hospital.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: Sr. V.P. & Area Manager (X6) DATE: 6/15/12

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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	Continued From page 1 report: Health and Safety Code Section 1280.1(c): For the purposes of the section "immediate jeopardy" means a situation in which the licensee's non-compliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Based on interview and record review, the hospital failed to ensure that Physician A maintained a high standard of surgical practice in accordance with the manufacturer's instructions for use of the particular Sharplan laser, OmniGuide Sidefire Adapter and fiber assembly employed during a surgical procedure performed on Patient 1. Physician A was not aware of the gas pressure used with the laser beam and did not use the laser beam on a perpendicular position to prevent the risk of complications. As a consequence, Patient 1 suffered a fatal vascular embolism (the entry of gas bubbles into the bloodstream which can stop the pumping of the heart) and died. THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WHICH PLACED THE HEALTH AND SAFETY OF PATIENT 1 AT RISK WHEN PHYSICIAN "A" FAILED TO DEMONSTRATE ABILITY TO PERFORM SURGERY USING A PARTICULAR LASER DEVICE BY NOT FOLLOWING THE MANUFACTURER'S INSTRUCTIONS FOR SAFE USE. THIS VIOLATION CAUSED OR WAS LIKELY TO CAUSE PATIENT DEATH OR SERIOUS		Immediate Action: Kaiser Foundation Hospital - Oakland/Richmond conducted a Root Cause Analysis (RCA) to review systems and processes that were in place. Based on our finding, the following immediate actions were taken. 1. Upon discovery of the event in question, the equipment involved in the event was immediately sequestered per Sentinel, Significant Event Policy and a forensics investigation was conducted by an outside consultant on 09/29 & 10/06/2010. Final report received 10/07/2010 and no equipment malfunction was identified. 2. Surgeon involved in case received Laser training on 10/13/10. 3. All physicians using lasers in the OR were required to complete online laser safety training and to attend vendor in-service training on specific lasers they will be using by 11/30/2010. 4. Laser privilege developed and approved by MEC, Head & Neck Surgery (H&NS), Urology, Ob/Gyn and Opthalmology on 10/06/2010. Surgery and Radiology on 11/03/2010 and Pediatric Neurosurgery had laser privileges in place. 5. 19 physicians granted temporary privileges upon completion of online laser safety training; pending final approval by Medical Executive Committee (MEC) by 12/14/2010. 6. "Laser Safety Checklist was added to pre-procedure re-verification checklist in OR 10/08/2010. 7. Laser Safety Officer completed training through Laser Institute of America (LIA) on 09/26/2010. 8. Laser Safety Officer newly appointed by Chief of Staff and Hospital Administrator on 09/27/2010 9. Laser Safety Committee was initiated and held first meeting in August 2010.	09/22/10 09/29 & 10/06/2010 10/03/2010

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	Continued From page 2 DISABILITY ASSOCIATED WITH A VASCULAR AIR EMBOLISM FOR PATIENT 1. Findings: Review of the medical record on 9/30/10 showed that Patient 1 was a healthy 29 year-old female who was scheduled for a hemangioma excision (removal of a congenital birthmark) on her left upper lip. She was admitted through the same day outpatient surgery service on [redacted]/10. Physician A performed the surgery using a laser machine leased to the hospital and operated by the laser company technician. Following the administration of general anesthesia, surgery was started at 3:40 p.m. The intraoperative report, dated [redacted]10, showed an OmniGuide laser, with helium at 70 psi was used during the surgical procedure. The "Operative Notes", dated [redacted]10, showed Physician A made, "a small incision in the mucosa of the left upper lip". A laser wand was then inserted into the incision and activated near the hemangioma. Almost immediately after the activation of the laser beam, the patient's face and neck began to swell up, "secondary to the helium gas of the laser device." A second stab incision was made in order to vent the trapped air. Shortly thereafter, at 3:50 p.m., the anesthesiologist noted the patient's falling blood pressure and end-tidal carbon dioxide (critical signs of loss of heart and lung function). A code blue was called and despite aggressive cardiopulmonary resuscitation, Patient 1 was declared dead at 5:20 p.m. The final autopsy report from the Coroner's Office indicates "arterial embolism" as the cause of death.		Systemic Actions: 1. Any new request for laser privileges are sent to the PeriOp director. The director sends an e-mail notification to requesting physician instructing them to complete the online laser safety course and contact the vendor for one on one laser equipment training. Annual Laser Safety training is required. 2. Prior to any surgical cases requiring laser, the OR manager verifies that all privileges are current. If they are not, cases are canceled. 3. OR staff receive laser safety education annually. 4. PRI Medical Technologies Technicians are required to have current Laser Safety Certificate. OR manager verifies current certification prior to case. 5. A comprehensive "Laser Safety Policy" was developed and approved by MEC on 01/2011. 6. Laser Safety Committee in place and meets at a minimum of four times per year. Monitoring: 1. Observational audits of "Time Out" on laser cases using new laser safety checklist are conducted by PeriOp Manager. No outliers were identified for monitoring 10/08/2010 - 01/30/2011. Ongoing random audits will continue to ensure sustained compliance. Results from monitoring activities were reviewed and reported to Risk Management & Patient Safety Committee, which reports to the Medical Executive Committee.	09/27/2010 - Annually 10/2010 - Ongoing 08/2010 - Annually 01/2011 Ongoing 10/08/2010-01/30/2011

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	Continued From page 3 The hospital staff reported on 9/30/12 that an OmniGuide Sharplan Sidefire Adapter (laser device) was used during Patient 1's surgery on [redacted]10. The manual for "Instructions for Use" issued by the manufacturer in November 2007, containing 30 pages, was reviewed on 9/30/10. The device consisted of a laser base machine operated by a technician and the laser flexible wand operated by the surgeon. The wand is flexible optical tubing containing the laser beam plus another channel carrying compressed helium gas flowing over the laser tip to cool it down. The helium gas pressure flow, expressed in pounds per square inch (psi), was set by the laser technician and could vary from 50 psi to 70 psi. The manual contained multiple warnings. On page 14, the instructions read, "Always monitor the vital signs of the patient for symptoms of gas embolism" and "Before the start of a medical procedure using the OmniGuide Sidefire Adapter and fiber assembly, to verify that the gas delivered to the system is of the proper type and pressure for the fiber assembly being used." The manual also warned, "...pressurized gas exits the fiber tip during the laser procedure and may cause gas embolism. To reduce the risk of embolism, do not bring the tip into contact with blood vessels or vascular tissue" and instructed to, "use the recommended fiber position where the fiber tip is perpendicular to the tissue and is at least 5 mm away from contact with the tissue. Be aware of this complication (inflation and trapping of air under superficial layers of tissue) when directing the gas stream." On page 16 of the Instructions for Use manual, the manufacturer cautioned the		Responsible Parties: Chief Nursing Officer Laser Safety Officer Chair, Credentials & Privileges Committee	

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providers to ensure that physicians performing laser procedures are trained in, "The use of the particular Sharplan laser being employed in the procedure" and in, "The use of the OmniGuide Sidefire Adapter and fiber assembly."

According to hospital's Director of Accrediting, Regulation and Licensing (AR&L), interviewed on 10/22/09 at 1:30 p.m., "the privileging in the ENT department is not per device but rather per condition or anatomic location". When asked how it is determined an ENT (ears, nose and throat) surgeon is qualified to use a new device, she replied, "Lasers are not part of the checking process that the operating room manager does. The question is can they do a tonsillectomy, not how." As for training, "the vendors do the training with the physicians" and "equipment has been used over 20 times this year." Further, the specific laser wand in use during the surgery, "would not signify a new piece of equipment, it is a new part of existing laser machinery".

The hospital credentialing file, reviewed on 10/22/10, showed Physician A was Board Certified in Ear, Nose and Throat Surgery (ENT). Regarding the surgical privilege for removal of hemangiomas, Physician A was approved on 9/2/09 to perform, "excision, skin lesions". There was no documented evidence that Physician A received training in the use of the particular Sharplan laser and the OmniGuide Sidefire Adapter and fiber assembly used for Patient 1, in accordance with the manufacturer's instructions for use.

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In an interview on 10/22/10 at 3 p.m. regarding this surgery, Physician A stated, "Nothing happened until the laser. The hemangioma was submucosal [under the outer skin surface], the mucosa was normal. So I made a stab incision, 1 centimeter, to the side of the tumor, inserted the tip of the probe and activated the laser. 15 seconds later, the lip began to swell up; helium was trapping in the soft tissues. I wanted to try making a second incision in order to let the air escape and that's when she coded." When asked if he was aware of the pressure the gas was delivered to the fiber assembly, Physician A replied, "I thought it was low pressure... that was my error." Physician A also stated that the laser technician set the pressure and, it was not the practice to call out or state the pressure (psi) used. "If I knew it was a high psi, I would have used another technique. I thought it was low pressure. That was my error." Physician A continued. When interviewed regarding the manufacturer's recommended position of the wand to prevent complications, Physician A stated he was not aware of any precautions at the time of the procedure" and stated , "No, it wasn't perpendicular." Physician A also stated that, "With this procedure we weren't protecting the laser tip from contact with the blood vessels, hoping that it [the laser] would shrink the tissue." During the interview, Physician A stated, "I did not read the manual [with instructions for use]."

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