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
	050417	A. BUILDING _____ B. WING _____	01/26/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUTTER COAST HOSPITAL	800 E. WASHINGTON BLVD., CRESCENT CITY, CA 95531 DEL NORTE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00252989, CA00252647, CA00251304 - Substantiated Representing the Department of Public Health: Surveyor ID # 25962, 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. Penalty number: #110008657 E 347 T22 DIV5 CH1 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.		CA00252989, CA00252647, CA00251304 Immediate Actions: Fire was extinguished by staff. Patient was evaluated for burn injuries. Patient was taken to ICU for observation. A root cause analysis was completed to determine the case of the fire. Immediate measures put into place for future patients were: Wet towels, low Bovie settings, use of protective Bovie holster, use of nasal cannula instead of mask and use of suction to reduce the amount of oxygen. Corrective Action: New policy, 130.206 titled "Fire Prevention and Management in an Oxygen Enriched Atmosphere" was developed and implemented based on Association of Perioperative Nurses (AORN) guidelines (2010 edition), Emergency Care Research Institute (ECRI) guidelines (most recent update 2006) along with other references for prevention of surgical fires/fire safety. Policy content includes: • use of moistened towels, sponges and drapes for all head and neck patients, • use of suction, • use of lowest possible Bovie settings, • stopping the use of oxygen one minute before cautery	1/7/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Eugene Lukas | TITLE: CEO | (X6) DATE: 11/29/11

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.

State-2567

POC accepted 12pm, Nov 29 with Carol Snoots Executive Administrative Assist — C. Blevins HFEN 2123

NOV 30 2011 By

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	Continued From page 1 Based on observation, staff interview and record review, the facility failed to develop, maintain, and implement a fire prevention policy and procedure to ensure the safety of a patient during a surgical procedure when a patient (Patient 1) received second degree burns to the face and chest, due to a flash fire. The fire was caused by the use of high flow oxygen through a face mask, which was ignited by an electrical cautery device used to coagulate wound tissue on the forehead. The failures to ensure procedures were in place to safeguard the use of oxygen and cautery during surgery, led to the burn injury of Patient 1. THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WITHIN THE MEANING OF HEALTH AND SAFETY CODE SECTION 1280.1 IN THAT IT CAUSED, OR WAS LIKELY TO CAUSE SERIOUS INJURY OR DEATH TO THE PATIENT, WHEN THE FACILITY FAILED TO ENSURE PATIENT SAFETY DURING A SURGICAL PROCEDURE RESULTING IN THE PATIENT RECEIVING SECOND DEGREE BURNS TO THE FACE AND CHEST. Findings: On 12/06/10, 12/17/10, and 12/21/10, the Department of Public Health received three reports that Patient 1 was burned on the face and chest due to an oxygen mask catching fire, ignited by a cautery source used for surgery on the forehead. The facility self-reports indicated that the surgery		• required use of cautery holster • use of 30% of oxygen for open delivery to the face. (Note: Due to the potential risk to patient safety, the policy was reviewed and approved by Medical Director of Surgical Services and distributed via email on 1/11/11 to Surgical Services Medical Staff vs. waiting until medical staff/board meetings for approval and implementation.) Listed below is a complete timeline for policy approval/implementation for policy #130.206 "Fire Prevention and Management in an Oxygen Enriched Atmosphere." 1. Policy developed by Director of Surgical Services. 2. Policy draft distributed to Surgical Services staff by Director of Surgical Services for review 3. Policy reviewed and approved by Medical Director of Surgical Services. 4. Policy presented and approved by Board of Directors. 5. Policy approved by CEO, and CNO. 6. Policy review with Surgical Services Staff during monthly department meeting. 7. Surgery medical staff orientation updated to include policy and educational material titled "Only You Can Prevent Surgical Fires" by the ECRI Institute.	12/23/10 12/23/10 1/6/11 1/6/11 1/7/11 1/7/11

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Continued From page 2

was on [redacted]/2010.

During an interview on 1/26/11 at 10:00 a.m., Administrator A stated that after the event occurred the facility did a root cause analysis and made changes to their fire prevention policy.

Review of the facility's root cause analysis and Action Plan titled " A Framework for Root cause Analysis and Action Plan" undated, on 1/26/11 at 10:10 a.m., indicated that on [redacted]10, Patient 1 was in the OR(operating Room) and had a basal cell carcinoma (skin cancer) removed from the right side of the forehead. At approximately 1:15 p.m., a fire was ignited that included surgery drapes around the patients head and the oxygen mask on the patient's face. OR staff removed the drapes and oxygen mask and extinguished the fire with water. The patient suffered second degree burns on her face and chest area.

On 1/26/11 at 10:30 a.m., review of "Biomed Investigation Of Surgical Fire, On [redacted] 2010:" indicated that on [redacted]/10, a fire was reported in OR 4, which started during a surgical procedure and involved the patient's oxygen mask and the surgical drapes around the patients head. The investigation indicated that the patient received intravenous anesthetics from a syringe pump. The patient also received metered oxygen from an oxygen mask that was attached to an oxygen flow meter that was part of the anesthesia machine. The oxygen mask used was an open style mask (it had five large openings) with fourteen feet of oxygen tubing. The Report indicated that the oxygen mask used was a

8. Policy distributed to medical staff. 1/11/11
9. Policy reviewed/approved by Surgery Committee. 1/19/11
10. Policy reviewed and approved by Medical Executive Committee. 1/26/11
11. Competency distributed to surgical services staff. 1/2011
12. Unit specific orientation updated to include policy #130.206 titled "Fire Prevention and Management in an Oxygen Enriched Atmosphere" for new employees in Surgical Services Department.

Responsible persons: Board of Directors, Chief Executive Officer, Chief Nursing Executive, Medical Director Surgical Services, Chief of Staff/Chief Medical Officer, Director Surgical Services

Monitoring Process:

1. Policy will be reviewed every two years and updated to reflect best practices.
2. Monitoring tool developed and implemented. 4 consecutive audits completed with 100% compliance.
3. Surgery Director and Supervisor conduct visual monitoring of procedures for compliance with policy.
4. Fire Safety in the OR is standing agenda item on Surgical Services monthly staff meeting.

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Continued From page 3

"Southmedic OM-1125-14 OxyMask." The Biomed investigation indicated that the fire was a small flash fire, which was most likely caused by the combination of electrosurgery and oxygen, in close proximity. The investigation report also indicated that there was always some risk of fire when electrosurgery are present, and more risk when both are present.

During an observation, on 1/26/11 at 10:40 a.m., of photographs taken by the facility after the incident, there was a picture of an opaque gray colored oxygen mask which had five holes of irregular shapes and charred black material melted into the mask. There was a picture of clear curled oxygen tubing next to the mask which had one end that was black, charred and melted together. There were pictures of the blue colored OR flooring, electrical cords and surgical drapes with black charred material on them. There was a picture, dated [redacted]/10, of Patient 1 with a reddened glossy face and right eyebrow which had partial area of hair removed and a white bandage covering an area on the right forehead.

During an interview on 1/26/11 at 1:55 p.m., CRNA (Certified Registered Nurse Anesthetist) B stated that the case started routinely, and Patient 1 was sleeping with an oxygen mask on and he was holding up her chin under the surgical drapes to ensure that the patient received adequate oxygen. CRNA B stated that Surgeon F yelled and there was a fire. CRNA B stated that he removed the oxygen mask and burnt his fingers. CRNA B stated that he thought there was too much oxygen flowing,

5. CRNAs to participate in bi annual fire safety training.
6. Orientation of new staff includes policy and education on fire safety in the operating room.
7. Medical Director of Surgical Services is notified of non-compliance with policy/safety guidelines of CRNAs and surgical services medical staff.
8. Director of Surgical Service is responsible for follow up/corrective action with staff that are non-compliant with policy/safety guidelines.

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	Continued From page 4 which was 10 liters, and the oxygen was gathering under the drapes. CRNA B stated that the part of the face that was burnt or was red was where the mask was. CRNA B stated that he had a high oxygen flow rate to the patient. CRNA B stated that there was no bovie holder for the bovie (cautery) on the surgical drape and they also used dry sponges. CRNA B stated that now the hospital policy is to stay below 25% oxygen flow rate and the excess air is suctioned out from under the drape. During an interview on 1/26/11 at 2:40 p.m., OR (Operating Room) Technician C stated that the surgical drapes were tented up by anesthesia and they did not use wet towels or sponges for the case. OR Technician C stated that the bovie was set high and she thought it could have been at a lower setting. OR Technician C stated that there was also no protective bovie holder on the field. OR Technician C stated that all of the sudden there was a flash and the surgeon was trying to put out the flames, with his hands and she poured water from a pitcher on the flames. OR Technician C stated that now they use wet towels or sponges, anesthesia decides how much oxygen we give, and the doctor talks to us about the lowest bovie settings he needs for more homeostasis. During an interview on 1/26/11 at 3:10 p.m., Circulating Nurse D stated that when the event happened, she was doing paperwork at the foot of the bed and heard Circulating Nurse E say that the patient was on fire and Surgeon F tried to smother the fire with his hands. Circulating Nurse D stated that since the fire in surgery, they used lower bovie			

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	Continued From page 5 settings, wet sponges, and nasal cannulas instead of masks and used suction on and off the field to suction oxygen buildup. During a telephone interview on 2/2/11 at 5:16 p.m., Surgeon F stated that the case started in a routine manner, and he removed a skin cancer from the patient's right forehead, started to cauterize a bleeder and there was a flash fire. Surgeon F stated that he pulled the drapes off the patient and dosed the patient with water. Surgeon F stated that the oxygen was at a high flow rate, but didn't know what the flow rate was, or what the percentage of oxygen was. Surgeon F stated that CRNA B had the sterile drapes tented up and was holding the patient's chin and the oxygen mask on the patient. Surgeon F stated that CRNA B moved the patient's chin and oxygen blew up toward the head of the patient, where he was operating and a flash fire developed. Surgeon F stated that he thought the problem was the higher flow oxygen that was pocketed under the drape which leaked out and caused the flash fire. During a telephone interview on 2/14/11 at 11:30 a.m., Patient 1 stated the physician told her, when she woke up after the surgery, that there had been an accident and that she had been burned during the surgery. Patient 1 stated that her lips were all scarred after the incident and that two of the scars were permanent. Patient 1 stated that she was in intensive care for two days after the surgery. Patient 1 stated that she now has trouble with her mouth, stated that she looked like a fish and it was hard to put her dentures in the right way. Patient 1			

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	Continued From page 6 stated that her face was red at times and that she had burns on her chest, one on her upper shoulder, one in the middle of her chest and one on the right side of her breast which was still sore. Patient 1 stated that the top of her left ear was burned as well. Patient 1 stated that her nose was stiff and dry like her lips and she lost 14 lbs. as at first it was difficult to eat a sandwich and she had to make sure it was real thin in order to eat it. Patient 1 stated that at first she did not want to venture out of the house the way she looked. On 2/14/11 at 12:00 p.m., review of the facility policy titled "Surgical Services fire Safety" that was in place before the incident, effective 3/5/2010, indicated steps to be taken if a fire occurred such as to turn off the medical gases, douse the patient with saline, remove the surgical drapes and use a smothering technique if needed to put out the fire. The policy described the use of alarms and evacuation procedures. The policy did not indicate measures to prevent fires in the operating room. On 2/14/11, review of a policy developed after the incident titled "Fire Prevention and Management in an Oxygen Enriched Atmosphere" with a start date of 1/7/11, indicated that fuel sources, ignition sources should be managed to prevent surgical fires and that prevention of surgical fires included using moistened towels and drapes and sponges on all patients who had procedures on their head or neck. Staff was to make sure that oxygen was not accumulating under the drapes and to use a suction to reduce the Oxygen enriched environment. The policy indicated to use the lowest			

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	Continued From page 7 setting of oxygen during the use of electrosurgical devices. Review of 2006 reference material, supplied by the hospital, titled "Only You Can Prevent Surgical Fires" dated 2/06, indicated to stop supplemental oxygen at least one minute before and during the use of electrosurgery, electrocautery or laser surgery, and to place electrosurgical electrodes in a holster when not active. The reference material indicated to use air or 30% or less of oxygen for open delivery to the face. Review of "Southmedic "on line product information indicated that the "OxyMask" , which was the type of mask used during the surgery, delivered 53% -85% oxygen on 10 liters oxygen flow. The facility's failure to develop, maintain, and implement a fire prevention policy and procedure to ensure the safety of a patient during a surgical procedure, which resulted in Patient 1 receiving second degree burns to the face and chest from a flash fire, 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(c).			

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