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
	050129	A. BUILDING ________ B. WING ________	02/02/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
St. Bernardine Medical Center	2101 N Waterman Ave, San Bernardino, CA 92404-4836 SAN BERNARDINO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00256145 - Substantiated Representing the Department of Public Health: Surveyor ID # 26774, 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. REGULATION VIOLATION: Title 22 70223 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. Based on interview and record review, the facility	POC Accept on 6/9/14 NI	Immediate Action: • Physicians and surgery staff immediately stabilized the patient. • Patient was immediately intubated to protect the airway • Surgeon called a plastic surgeon to assess the burns. • Plastic surgeon arrived and assessed patient • Wound care clinic surgeon arrived and assessed the patient. • Arrowhead Regional Burn unit Medical Director was called within 90 min. to arrange transfer to their Burn unit. • Patient was transferred to the ICU pending transfer to Arrowhead Regional (ARMC). • Patients board and care facility was called following the event. • Patient was transferred to ARMC burn unit • Surgeon at ARMC disclosed event to patient when he was stable. • Operating room (OR) staff verbally educated that for all surgeries	1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11 1/14/11

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: Clinical Quality Coordinator (X6) DATE: 6/5/14

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 9

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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failed to follow their policy and procedure for fire prevention in the operating room, when using an electrosurgical unit (ESU). This failure resulted in a flash fire during the removal of a squamous cell carcinoma from Patient A's neck and Patient A sustaining second degree burns to his eyelids, eyebrows, forehead, cheeks and anterior 1/3 of his tongue. As a result, Patient A had to be transferred to the burn unit at Arrowhead Regional Medical Center, where he underwent plastic surgery involving a skin graft from his thigh to his face.

FINDINGS:

Patient A was a 57 year old male admitted for out patient surgery at St. Bernadine Medical Center on [redacted] 2011. His diagnoses included: schizophrenia (a thought disorder), hypertension (high blood pressure), hypothyroidism, (low thyroid hormone), history of congestive heart failure (poor pumping action of the heart creates fluid build up in the lungs and extremities), osteoarthritis, (chronic degenerative disease of joints), and presence of a pacemaker (a device implanted into the chest wall that delivers electrical stimulation for people with slow heart beats).

Documentation showed Patient A had developed a lesion on his neck that the physician determined was a type of cancer called squamous cell carcinoma, which did not appear to have metastasized (spread). The surgeon scheduled Patient A for an outpatient procedure called a "wide excision of a neoplastic (cancerous) lesion on the base of the neck;" the plan included Patient A returning to his home on the same day.

(cont)

above the xyphoid, wet sponges would be used in the field

- OR staff verbally educated that chloroprep would no longer be allowed for head and neck surgery in oxygen rich environment where cautery is planned. — 1/14/11
- OR staff verbally educated that draping for head and neck surgery will include venting and tenting to reduce risk of oxygen concentration. — 1/14/11

Permanent Action: — 1/14/11

- All surgeries above the xyphoid, wet sponges will be used in the field.
- All surgeries above the clavicle in an oxygen rich environment where cautery is planned, a non-alcohol prep solution will be used. Chloroprep will no longer be allowed for head/neck surgery. "Skin Prep" policy. — 1/14/11
- Draping for head/neck surgery to reduce risk of oxygen concentration will follow the "Surgical Services Fire Plan" policy. — 1/18/11

Monitoring:

Periop Director or OR Educator

(over)

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		(cont)	will conduct audits to ensure compliance.	
	A review of the operative report by Doctor 1 dated [redacted] 2011 at 10:15 AM, indicated that there was a complication during the surgery when, "A flash flame associated with the use of the cautery (an instrument that destroys tissue by a heat producing electrical current), resulting in second degree burns to the patient's face, including the right cheek, the tip of the tongue, lips...eyelid, eyebrow, forehead and top of head, which all appeared to be second degree burns." The surgeon further documented, "After elliptical incision made, cautery was used to begin excision and immediately flash flame occurred when it ignited the 4x4 sponge and paper drapes, and mask on the face...the patient remained awake. Second degree burns were noted on both cheeks, forehead, eyebrows, lids and top of the head and tip of tongue. The patient was then intubated (a tube placed down the throat to maintain an airway) and he was re-prepped (new equipment was used)." After eddressing the burns, the surgeon completed the surgery on Patient A's neck.		• Discussion @ Anesthesia Division regarding Fire Safety measures. Fire Risk Assessment tool to be used on each case and documented in the record. Anesthesiologists to use intubation when possible for head/neck cases with cautery. monitoring Peri-op Director and OR staff and physicians will review records for Fire Risk Assessment. • OR Staff education by vendor: "Fire Safety and use of Skin Preps".	2/4/11 2/4/11
	A review of the anesthesiologist notes dated [redacted] 2011 at 9:00 AM showed that Patient A was given medications to sedate him versus using general anesthesia, and an oxygen mask was applied instead of intubating the patient. The anesthesiologist wrote that after the initial incision, "...Bovie (brand of cautery) was used and scrub RN (registered nurse who assists the surgeon) claimed spark ignited up to operative gauze and flew up to the face mask. Drapes (paper coverings placed to maintain sterile field) and mask [oxygen]		• Revised Electrosurgical Unit (ESU) and Safety measures" policy + procedure to include keeping ESU at lowest possible power setting and other safety measures. Approved Patient Care Services Committee Approved Cardiology section Approved Patient Care council Approved Cardiology section	2/2011 2/2011 4/27/11 3/2011 4/27/11

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	immediately taken out and face flushed with saline... entire event happened in less than 30 seconds. Patient sustained second degree burns over the face with both eyelids singed. Plastic surgeon called to assess burns. Both eyes checked no injury sustained, but anterior of tongue also sustained first and second degree burn...anesthetic changed to general anesthesia...wound clinic surgeon came in and assessed patient. Advised to intubate patient since there is some tongue swelling to protect airway in case swelling gets worse." During review of the plastic surgeon's documentation regarding his findings during the intraoperative consultation on [redacted] 2011, the following was noted, "Upon arrival to the operating room, the patient has been intubated. He has what appears to be a second degree burn to his right cheek, forehead, brow, eyelid, nose, mouth, perioral (area around the mouth), and one third of the anterior tongue. There is some erythema (redness) and the total body surface (TBSA- a standardized scoring of burn areas using percentages) is approximately 2 percent." He recommended that the surgery be completed quickly and Patient A be transferred to the Burn Unit at Arrowhead Regional Medical Center (ARMC). The surgery was completed without further incident and Patient A was transferred to the Intensive Care Unit pending his transfer to the Burn Unit at ARMC. Patient A arrived at ARMC Burn Unit Intensive Care	(cont)	Approved medicine Division Approved OBGYN Division Approved surgery Division • Revised "Laser safety" policy + procedure to require a basin of water be available for all laser cases. • Revised "Skin Preparation" policy + procedure, #6 was changed to state "surgical procedures performed above the clavicle are prepped with an approved skin antiseptic." #6.1 was added "Chloraprep may not be used as a primary preparation on procedures performed above the clavicle. #8.1 was added: if clipping is not appropriate for surgery, long hair in the sterile field, prepped with water-soluble surgical lubricant is applied prior to draping." Approved Patient Care Services Committee. Approved Patient Care Council Committee + CNE. __monitoring__ Peri-op Director or OR Educator	5/4/11 5/11/11 7/8/11 2/2011 3/2011 3/11 4/11

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	Unit (ICU) on [redacted] 2011 at approximately 2:30 PM, with diagnoses of, "2% TBSA burns to face." Patient A's condition was listed as "critical". He was placed on a ventilator (a machine used to assist respirations) as a precaution to maintain his airway. In addition, he received intravenous fluids and had a nasogastric tube (tube placed through the nostril down into the stomach, through which liquid medication and nutrition could be administered), until he could safely tolerate an oral diet. Patient A's facial wounds were treated, and his pain managed with intravenous morphine (a narcotic pain medication). Patient A was extubated (the tube in his airway was removed, and he was breathing on his own) on the second day in the burn unit.	(cont)	will ensure knowledge of topic is tested in annual OR staff competencies and/or fire drills.	7/11
			• Revised 'Nursing Operative Record' to include "Fire Risk Assessment" monitoring Peri-op Director or OR Educator will audit charts for compliance.	2/11
	On [redacted] 2011, the plastic surgeon reassessed Patient A for surgery, but the patient refused. He had been combative, and required one to two people in constant attendance with him since admission. On [redacted] 2011, he agreed to the procedure, and was taken to the operating room for a "tangential excision and split thickness graft to the right eye with canthopexy." In this procedure, the surgeon removed only non-viable tissue from the burned area. The eyelid was then sutured (sewn) to provide support for the eyeball, and a skin graft was taken to include the epidural (outer layer of skin) and partial dermal layer (middle layer of skin) from his thigh. Patient A's skin graft was not being rejected and on [redacted] 2011, he had his graft takedown done.		• Revised OR competencies for use of skin preps to reflect changes in policy & procedure practice.	3/11
			monitoring: Peri-op Director or OR Educator will include in annual OR staff competencies and/or fire drill.	7/11
			• OR staff Education: "Dampening of Surgical Fire" Fire Drill briefing and de-briefing included.	3/9/11
	In the course of his hospitalization at ARMC,		monitoring Peri-op Director or OR Educator will include in annual fire drill.	6/11

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	Patient A developed "neck cellulitis (inflammation)" on [redacted] 2011, which was treated with an intravenous antibiotic. Some crusty lesions were observed on the perioral region on [redacted] 2011, and the resulting culture and sensitivity indicated that it was positive for methicillin-resistant staphylococcus aureus (MRSA- a bacterial infection resistive to multiple antibiotics). The lesions improved after Bactroban, an antibiotic, was initiated. On [redacted] 2011, the burn unit notes described "facial wounds had a gritty build up around the lip, despite every day wound care." This had the potential to result in uneven scar tissue formation on his face. Patient A was discharged to a skilled nursing facility on [redacted] 2011. On [redacted] 2011 at 9:00 AM, an unannounced visit was made to St. Bernadine Hospital Medical Center to investigate an entity reported event described as, "Flash fire occurred, lasting less than seconds and involving the use of Bovie cauterization device in our OPSC (outpatient surgical center). The involved patient sustained thermal burns to his face and neck and was transferred to ARMC burn unit for higher level of care." During an interview with the risk manager at 9:15 AM, she stated the following, "The anesthesiologist used a mask to deliver the oxygen. The patient had a history of congestive heart failure. The patient's face and head were draped with paper drapes. They used alcohol prep. The P&P (policy and procedure)		• Revised "Universal Protocol (Marking of Operative/Procedure site + Time out) policy and procedure to add a "Pause for Fire Risk Assessment." Approved: Anesthesia Division and Surgery Division. Monitoring: Peri-Op Director or OR Educator and Anesthesia Division will ensure knowledge of topic tested in annual OR staff competencies and/or fire drill. • Created a "Fire Risk Assessment" tool for surgeries using oxygen rich environment with cautery or laser. • OR staff education on Fire related "Laser Safety" • Created "2011 Fire in the OR competency" training + test • OR staff education with mock fire scenarios and "Fire Drill" • OR staff education: "2013 Fire Drill Review Information" to include "Fire Risks in OR" (over)	4/11 5/11 7/11 7/11 4/11 5/6/11 7/11 6/11 6/13

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	says not to, but to let it dry 3 minutes, and they let it dry at least 10. The surgeon made an incision in the neck and when he used the Bovie electric cautery and touched the skin, it arced and caught the surgical 4x4 sponge on fire. The nurse threw the 4x4 off but the paper drapes had caught fire due to the oxygen under the drapes. The drapes were also thrown off. It all took less than 8 seconds. The patient (Patient A) had his face singed from chin to hairline with second degree burns. He was quickly intubated and put under general anesthesia to control pain and the operative situation. The surgeon called the plastic surgeon and another surgeon who is a wound specialist to assess the best course for the patient. Even though there was no inhalation burns or airway compromise, there was some swelling from tongue, they contacted the burn unit at ARMC, started a Profanol drip (inducing sedation) and completed surgery." During an interview with the RN director of the operating room (OR) at 10:00 AM, she stated, "These were all experienced people with over 30 years. The biomedical engineers checked out the equipment and found nothing wrong. After the incident, we sequestered all machines, drapes, gauze that were involved and started with a fresh prep for the patient." The RN OR Director stated, "Fire is always a risk in an OR. They used an 8 minute dry time and the recommended is 3 minutes [reference to the alcohol based prep product]. The sponge was 4 or 5 inches away from the area the surgeon was using the Bovie and it was dry. Since the machine [Bovie]	(cont)	Monitoring - Peri-Op Director or OR Educator - will include in annual competencies on fire drill. • OR Annual Competency • Perioperative Services 2013 Resource Manual includes section on "Fire Safety" Monitoring: Peri-Op Director or OR Educator will include in Peri-operative Services Resource Manual to prepare for competencies • Review with Anesthesiologists the 2009 ECRI recommendations regarding "Surgical Fire prevention" and the AORN recommendations regarding surgical fire safety. Monitoring: Peri-op Director or OR Educator or designee to audit compliance with ECRI and AORN recommendations regarding surgical fire prevention.	7/13 5/14

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checked out, the oxygen mask may have had a minimal, undetected leak due to Patient A's head being turned towards the side. We believed the oxygen caused the arc."

A review of the facility's policy titled, "Skin Preparation" dated 1/96, documented the following regarding alcohol preps:

a. #6 "Alcohol based preps will be allowed to dry prior to applying sterile drapes."
b. #8 "Allow Chloraprep/Duraprep to dry for three minutes prior to applying drapes, for in combination with the use of cautery, laser and the presence of oxygen."

A copy of the package labeling on the Chloraprep used on Patient A, indicated it was a "26 ml applicator". Under the picture of a flame on the packet the following was written, "Do not use a 26 ml applicator for head and neck surgery....solution contains alcohol and gives off flammable vapors... do not use on an area smaller than 8.4 x 8.4 inches (1 inch =2.54 cm). Patient A's wound measured 4 cm x 1 cm (1.6 inches by 0.4 inches).

A review of the facility's policy and procedure titled, "Surgical Services Fire Plan" dated 7/94, listed the guidelines for using ESU (Bovie), flammable materials (alcohol prep) and oxygen as follows:

a. #11.1 Operating room is an oxygen rich environment.
b. #11.2 Elements of the fire triangle exist: heat, fuel and oxygen.

Provider's Plan of Correction (handwritten):

• Anesthesiologists to create information reminder sheet to include requiring communication between anesthesiologist and surgeon when open oxygen source is used and surgeon to communicate to anesthesiologist when ready to use cautery. Information sheet to be presented at next Anesthesia Division meeting. — 6/14

Monitoring: Anesthesiology chair or designee to have ~~sheet~~ laminated information placed by Anesthesia machines.

• OR 2014 General Competency Assessment and Test "Fire Safety". — 6/14

Monitoring: Peri-Op Director or OR Educator will include in annual OR staff Fire Drill.

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c. #11.5 If oxygen or nitrous oxide is being used during head and neck surgery, coat hair near the surgical site with water soluble lubricant.
d. #11.6 Allow alcohol preps to dry (time frame not specified) before draping to ensure dissipation of alcohol vapors.
e. # 11.7 Minimize the build up of oxygen and nitrous oxide beneath drapes by tenting or incising drapes to allow dissipation of the gasses.

A review of the facility's policy and procedure titled, "Electrosurgery Unit and Safety Measures" dated 5/09, did not include stopping the oxygen flow for at least a full minute before utilizing the Bovie.

In addition, during the interview conducted with the RN OR director, she stated that Patient A was receiving 60% concentration of oxygen during the procedure.

The facility's failure to follow its written policies and procedures to prevent the surgical fire on the patient's face has caused, or is likely to cause, serious injury or death to the patient.

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).