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
	050069	A. BUILDING _____ B. WING _____	02/26/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
St. Joseph Hospital	1100 W Stewart Dr, Orange, CA 92868-3849 ORANGE COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00427098 - Substantiated Representing the Department of Public Health: Surveyor ID # 29558, 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 1280.3: 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 Section 1279.1 (b): For purposes of this section, "adverse event" includes any of the following: (5)(c) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility. Health and Safety Code Section 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. The CDPH verified that the facility informed the patient or party responsible for the patient of the adverse event by the time the report was made.		This Page Intentionally Blank RECEIVED FEB 10 2016	

Event ID:GG0911 1/14/2016 8:06:00AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Director Regulatory Accreditation TITLE (X6) DATE 2/10/16

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

2/11/16
OC 295358

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	DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY: Title 22, Division 5 Chapter 1, Article 3, §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 medical record review, the hospital failed to implement its policy and procedure (P&P) related to prevention of surgical fires during Patient 28's surgical procedure. The surgical team failed to communicate among themselves regarding the patient's high risk for fire hazards prior to the procedure and continued use of oxygen prior to the use of the electrosurgical unit (ESU, a unit delivers high voltage and power that can cause serious electrical burn) and failed to ensure the surgical drapes were placed in a proper position, allowing the ventilation of oxygen underneath the drapes as per the hospital's P&P. These failures resulted in a fire during Patient 28's procedure, causing a second degree burn (partial thickness burn involving the epidermis and part of the dermis layer of skin, may result in scarring) to the patient's face and a third degree burn (full		**Plan of Correction** Immediate review of current policy and procedure with Operating Room Staff and Anesthesiologist. OR Staff will have face to face education initiated 1/14/15. Anesthesiologist will be provided information by the Medical Director Anesthesiology initiated 1/15/15. **Responsible Parties** Director Surgical Services Medical Director OR Medical Director Anesthesiology **Monitoring** A minimum of 10 procedures per month for 3 months will be audited to ensure compliance with Prevention of Surgical Fires Policy (CLN-240). Any identified incidents of non-compliance will be immediately brought to the attention of staff for coaching. Identified incidents of non-compliance will be reported to the Quality Safety Committee of the Medical Staff for further recommendations. RECEIVED FEB 10 2016	3/10/15

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	thickness burn involving destruction of the entire skin, extend into fat tissue, muscle or bone, and often causing much scarring) to the patient's nasal passages (a channel for air flow through the nose). Patient 28 was transferred to a burn center at another acute care hospital for further specialty care of the burn. Findings: The hospital's P&P titled "Prevention of & Response to Surgical Fires" (revised 7/14) showed all staff/personnel will follow fire safety guidelines. Precautions used during procedures include the following: * To place drapes to allow for venting of gas to prevent accumulation of oxidants such as oxygen, which could lead to an enriched atmosphere that is more conductive [sic] to fire. Tent drapes to allow gases to drain away from OR (operating room) table. * To assess the patient for fire risk for each surgical procedure, communicate fire hazard levels 3 or 4 to all surgical team members prior to the start of the procedure, implement the plan of care based on the fire risk, and then document in the patient's intra-operative record. - For standard fire precaution for all fire risk assessment levels, the plan of care includes to prevent the accumulation of oxygen enriched atmospheres, nitrous oxide, and flammable gases under surgical drapes or within areas where		**Plan of Correction** Operating Room nursing staff educated face to face on new process to announce the fire risk assessment immediately after timeout. Initiated 1/15/15 **Responsible Parties** Director Surgical Services Medical Director OR Medical Director Anesthesiology **Monitoring** A minimum of 10 procedures per month for 3 months will be audited to ensure compliance with fire risk assessment completed and announced following the timeout. Any identified incidents of non-compliance will be immediately brought to the attention of staff for coaching. Identified incidents of non-compliance will be reported to the Quality Safety Committee of the Medical Staff for further recommendations. RECEIVED FEB 10 2016	3/10/15

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	electro-surgery is performed. - For high risk levels (rating 3 or 4), standard fire safety precautions and environment risk assessment are to be followed. All surgical team members are to verbally communicate the fire hazard levels 3 or 4. * To stop the supplemental oxygen at least one minute before and during the use of a laser, ESU or other ignition source to allow for a return to ambient air conditions when used for procedure above the xiphoid (a small cartilaginous process of the lower part of the sternum). If the oxygen cannot be turned off, decrease the flow of oxygen to the minimal possible. Review of Patient 28's medical record was initiated on 2/23/15. The patient was admitted to the hospital on 1/13/15, as an outpatient for an excision procedure of a melanoma (a type of skin cancer) to the right cheek. The patient had no history of respiratory (lung or airway) or cardiac (heart) disorders, no history of breathing problems related to allergies, no history of obstructive sleep apnea (an obstructive of upper airway when the patient is asleep). The patient had had extensive sinus surgery in the past and underwent daily irrigation due to fungal sinusitis (infection of sinus). The OR Case Record dated 1/13/15, showed Patient 28 was brought to the OR on 1/13/15 at 0800 hours. The patient was identified as a high risk for fire hazards. The patient's surgical site fire risk assessment score was 3, which included one		**Plan of Correction** For procedures above the xiphoid: -The Anesthesiologist or RN (if non-anesthesia case) will be educated on: • Turning off any open oxygen source for at least 1 minute prior to the use of Electrical Surgical Unit or other ignition source. When oxygen cannot be turned off it will be decreased to the minimal possible to maintain the patient oxygen saturation. Initiated 1/14/15 • Communicate to the surgeon/procedural physician and team that the open source oxygen is in use. Initiated 1/14/15 • Take steps to clear any potential pooled or trapped oxygen. Initiated 1/14/15 Continued Next Page	3/10/15

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	score from each of the following categories: surgical site above the xiphoid, open oxygen source, and available ignition source such as an ESU. The OR Case Record also showed the Fire Risk Assessment-Plan of Care for high fire risk included to verbally communicate the fire hazards with all surgical team members prior to the start of the procedure. Patient 28's Anesthesia Record dated 1/13/15, showed the anesthesia was started at 0800 hours and the incision time was at 0821 hours. The patient received oxygen at 0.5 liter per minute via nasal cannula (a device for delivering oxygen by way of two small tubes that are inserted into the nostrils) at 0815 and 0820 hours. Documentation showed shortly after the surgeon started to use the ESU, flames were seen on the drapes. The surgical drapes and oxygen cannula were removed and the oxygen was turned off. The Operative Report dictated by MD (Medical Doctor) 1 on 1/13/15 at 1005 hours, showed a monitored anesthesia care was arranged for Patient 28 per the anesthesiologist. The patient's right side of face was prepped for the procedure. The incision was made around the perimeter at the pre-marked site. When the lesion was about to be elevated from the inferior (lower) portion of the cheek with the needlepoint cautery (an instrument connected to ESU, used to destroy abnormal tissue by burning), the fire was noted at the surgical site. The surgical drapes were immediately withdrawn. The plan was		**Responsible Parties** Director Surgical Services Medical Director OR Medical Director Anesthesiology **Monitoring** A minimum of 10 procedures above the xiphoid will be audited per month for 3 months to ensure compliance with Open Oxygen use, communication with team regarding oxygen and ESU initiation and steps taken to clear any potentially trapped oxygen. Any identified incidents of non-compliance will be immediately brought to the attention of staff for coaching. Identified incidents of non-compliance will be reported to the Quality Safety Committee of the Medical Staff for further recommendations. Continued on Next Page RECEIVED FEB 10 2016	

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	to provide treatment for the fire in the airway. The ENT (otolaryngologist, a physician who specialized in diagnosis and treating of ear, nose, and throat) Consultant came to the OR for further examining of the patient. The patient's eyes were irrigated with BSS (a sterile irrigating solution) and the patient reported her vision was good. However, review of the medical record failed to show documented evidence the surgical team members had communicated among themselves regarding the patient's high risk for fire hazards as identified prior to the start of the patient's surgery as per the hospital's P&P. There was no documented evidence of any surgical team communication related to discontinuing use of oxygen prior to the use of the ESU. There was no documented evidence showing how the surgical drapes were placed to prevent pooling of oxygen under the drapes to avoid flame conductivity as per the hospital's P&P. The Operative Report dictated by the ENT Consultant dated 1/13/15 at 0924 hours, showed the patient complained of burning to the face and nose. The patient had extensive burns over the cheeks and lips and extensive burns and char in the nasal cavity (the right side greater than the left side), extending from the anterior (front) nasal cavity to the posterior (back) cavity. There was mild char in the nasopharynx (the area connected the nasal cavity to throat). The ENT Consultant recommended an overnight observation in a monitored bed to evaluate airway patency and rule out any delayed edema (swelling); steroids (a		**Plan of Correction** Each procedural department will review the draping process for procedures above the xiphoid to reduce the risk of pooled or trapped oxygen. Initiated 1/28/15 **Responsible Parties** Director Surgical Services Director Cardiovascular Interventional Lab **Monitoring** A minimum of 10 procedures per month for 3 months will be audited to ensure compliance with established draping process. Any identified incidents of non-compliance will be immediately brought to the attention of staff for coaching. Identified incidents of non-compliance will be reported to the Quality Safety Committee of the Medical Staff for further recommendations. Continued on Next Page	3/10/15

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	medication used to treat for inflammation) to be tapered for airway protection; starting broad-spectrum antibiotic or Unasyn (an antibiotic); and using Bactroban (a topical antibiotic) ointment within the nose. The patient would need to be discharged with Augmentin (an antibiotic) due to the extensive burns in the nasal cavity, would need to follow up with the patient's primary ENT as she would likely require further debridement and nasal care due to risk of stenosis (an abnormal narrowing) and scarring, development of synechiae (bands of scar tissue, or adhesions). The Progress Note dated 1/13/15 at 1534 hours, showed Patient 28 was seen in the ICU (Intensive Care Unit). The patient had few complaints at this time with the exception of losing her sense of smell. The ENT Progress Note dated 1/13/15 at 1820 hours, showed Patient 28 was noted with loss of sense of smell. The patient had possible need nasal splints in an effort to prevent future synechiae. The ENT Progress Note dated 1/14/15 at 1738 hours, showed Patient 28 had numbness to the nose, lips, and cheeks. The patient also had increased nasal congestion and edema to the left nostril, with clear rhinorrhea (running nose) mixed with black material, persistent anosmia (loss of smell), and extensive char in the nostrils. The Discharge Summary dictated on 1/15/15 at 1141 hours, showed Patient 28 maintained in place		**Plan of Correction** Surgeon/Procedural Physician will communicate to the anesthesiologist and team the initial use of the Electro Surgery Unit or other ignition source. 1/28/15 **Responsible Parties** Director Surgical Services Director Cardiovascular Interventional Lab **Monitoring** A minimum of 10 procedures per month for 3 months will be audited to ensure compliance with physician to physician communication. Any identified incidents of non-compliance will be immediately brought to the attention of staff for coaching. Identified incidents of non-compliance will be reported to the Quality Safety Committee of the Medical Staff for further recommendations.	3/10/15

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	in the intensive care, was seen in consultation with the intensive care specialist, had been on Unasyn intravenously (an infusion of medication directly into the patient's vein) and topical antibiotic for internal nose and Silvadene (a topical antibiotic, used to prevent and treat of infection in second and third degree burns) cream for the face. The patient was transferred to a burn center at another acute care hospital for further specialty care for the burn of the patient's nasopharynx. Review of the patient's history and physical examination from the burn center at another acute care hospital dated 1/16/15, showed Patient 28 was admitted to the Burn Unit for higher level of care due to airway and facial burns. The patient had difficulty breathing through her left nostril. The patient's left nostril was appeared to be narrowed with granulation (new tissue and tiny blood vessels form on the surfaces of a wound during the healing process tissue). The passage along the left nostril was very tight. The patient had partial thickness burns to her nose, perioral (tissue around the mouth), lips, cheeks, and anterior of the ears. The patient had full thickness burns to the nasal passages. Review of the Discharge Note from another acute care hospital dated 1/20/15 (7 days from the patient's procedure day and sustaining the burns to the face and nose), showed the ENT Consultant had performed a nasal endoscopy (an evaluation of the nasal and sinus passages with direct vision using a magnified high-quality view) procedure for the patient. The finding showed the patient had		This Page Intentionally Blank	

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	extensive mucosal injuries with scabs, melted plastic, and soot (a black powdery or flaky substance consisting largely of amorphous carbon, produced by the incomplete burning of organic matter) diffusely to the bilateral anterior nasal cavities. The left nasal cavity had a complete stenosis (narrowing or stricture of a passage) with scarring, just anterior to the middle turbinate (a long, narrow and curled spongy bone that protrudes into the breathing passage of the nose). Extensive debridement and suctioning were performed and nasal trumpets (a soft rubber or plastic hollow tube that is passed through the nose into the posterior pharynx [the part of the throat that lies between the mouth and the voice box] to secure an open airway) size 28 was placed in the bilateral nasal cavities. Further review of the Discharge Note showed Patient 28 complained of blurry vision that improved with eye rubbing and blinking. The patient wore hyperopic glasses, and was given artificial tears. The ophthalmology was consulted. The patient's facial burn wound culture had few bacteria (gram positive coccibacilli, staphylococcus aureus species, coag negative staph), and few yeast. The section of Physical Exam on Day of Discharge of the Discharge Note showed Patient 28's face covered with burn netting and dressings. The patient had nasal trumpets in place. The section of Discharge Instruction of the Discharge Note showed Patient 28 would be discharged home with home health (the medically-related services provided to patient by a		This Page Intentionally Blank	

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	health care professional in the patient's home setting). The patient would have no swimming or outdoor activities until wounds were healed. The patient would apply Santyl (an enzyme, topical debridement) ointment to open areas on face and mupirocin (same as Bactroban) to nasal and the right cheek incision, Vaseline gauze and burn netting daily. The patient would take pain medications 30 minutes prior to coming to burn clinic and wear a well brimmed hat while outside to protect the face. The discharge medications included amoxicillin-clavulanate (same as Augmentin). An interview was conducted with RN (registered nurse) 1, ORT (operating room technician) 1, and Patient Safety Officer on 2/23/15 at 1500 hours. ORT 1 and RN 1 were asked about the OR fire that occurred on 1/13/15, involving Patient 28. RN 1 stated the fire risk assessment was based on 4 categories, including incision above the xiphoid, use of alcohol, use of oxygen, and use of cautery. The total fire risk assessment score would be added from these categories, one point for each category. Patient 28's total fire risk assessment score was 3, which indicated the patient was at high risk for fire hazards. RN 1 stated the communication related to the patient's high fire risk assessment would be conducted between the physicians. She was not involved in the communication of the patient's fire risk assessment and the use of oxygen and ESU. She stated she did not hear the surgeon and anesthesiologist communicate about the patient's high fire risk, use of oxygen, and use of ESU.		This Page Intentionally Blank RECEIVED FEB 10 2016	

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	A follow-up interview was conducted with RN 1, ORT 1, Patient Safety Officer, and Surgical Services Clinical Manager on 2/25/15 at 1150 hours. RN 1 and ORT 1 were asked about the use of oxygen and draping of the patient in the OR on 1/13/15. RN 1 stated when she went into the OR, the oxygen cannula was already placed on the patient. ORT 1 stated for the patient's procedure, the spilt surgical drapes were placed covering Patient 28's left side of face including the oxygen cannula and OR table. The drapes were not set up to allow venting of the oxygen to prevent the flame conductivity. An interview was conducted with the Director Risk management and Patient Relations, Patient Safety Officer, and Director Regulatory & Accreditation on 2/15/15 at 1310 hours. When asked about the cause of the OR fire occurred on 1/13/15, to Patient 28, the Director Regulatory & Accreditation stated the oxygen was entrapped. An interview was conducted with MD 1 and Director Risk management and Patient Relations on 2/25/15 at 1525 hours. MD 1 stated he did not want to use the oxygen for this case. He did not know why Patient 28 needed the oxygen. The patient's airway was managed by the anesthesiologist. He stated he did not discuss the use of oxygen with the anesthesiologist. Time out for fire safety was not conducted. The cause of the fire was pooling of oxygen underneath the surgical drapes, which was		This Page Intentionally Blank	

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	more conducive to fire. 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 1280.3(g).		This Page Intentionally Blank	