

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050329	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/06/2018
NAME OF PROVIDER OR SUPPLIER CORONA REGIONAL MEDICAL CENTER-MAGNOLIA		STREET ADDRESS, CITY, STATE, ZIP CODE 800 S Main St, Corona, CA 92882-3420 RIVERSIDE COUNTY		
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	<p>(5) Environmental events, including the following: (C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.</p> <p>A002 1279.1 (c) HSC Section 1279</p> <p>The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.</p> <p>The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.</p> <p>Health and Safety Code section 1280.3(g)</p> <p>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.</p> <p>Health & Safety Code Section 1280.3 (a): (a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars (\$75,000) for the first administrative penalty, up to one hundred thousand dollars (\$100,000) for the second subsequent administrative penalty, and up to one</p>			

Event ID:OF7711

3/19/2018

4:40:38PM

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	<p>hundred twenty-five thousand dollars (\$125,000) for the third and every subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.</p> <p>Surgical Services General Requirements, Title 22, Division 5, Chapter 1, Article 3, Section 70223(b)(2):</p> <p>A committee of the medical staff shall be assigned responsibility for 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.</p> <p>Based on interview and record review, the facility failed to ensure their facility policy and procedure and facility-accepted Association of Peri-Operative Registered Nurse (AORN) standard recommended practices for electro surgery were followed for one patient (Patient A) by failing to ensure the ESU (cautery device) was set to the lowest level setting required for the surgery, as directed by the surgeon. These failures resulted in second and third degree</p>		<p>Policy and Procedure</p> <p>1. A process change was made to include the RN Staff confirming the power setting before activating use of the ESU, for cases with a level three fire risk. This ensures that the lowest level setting required for the surgery is used, as directed by the Surgeon.</p>	9/25/15

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	<p>burns to the left side of the patient's face and neck. The patient had to be transferred to another facility for a higher level of care, and underwent additional surgery for skin graft to the burned areas.</p> <p>Findings:</p> <p>During the investigation of an entity reported incident on August 27, 2015, at 2:45 p.m., a review of the patient's clinical record revealed the following.</p> <p>Patient A was admitted for Day Surgery on August 26, 2015, with a diagnosis of lipoma right forehead (a growth of fatty tissue that develops under the skin). Patient A was scheduled for an excision of right forehead mass (a lump).</p> <p>The Anesthesiologist's documentation dated August 26, 2015 at 10:20 a.m., indicated the risks, benefits, alternatives, and complications of monitored anesthesia care were discussed with and accepted by the patient. "The patient wants local with monitored anesthesia care (an anesthesia technique using local anesthesia, sedation, pain medication, and oxygen, if needed) only and will take general anesthesia only if needed as a last choice. I suggested general anesthesia and will do monitored anesthesia care since the patient wants it that way and patient understands the risks of doing facial surgery under monitored anesthesia care and possibility of increased fire hazard compared to general anesthetic with endo-tracheal tube...spoke to surgeon and he wants MAC (monitored anesthesia care) and he wants it particularly</p>		<p>Education and Training</p> <p>1. Re-educate OR Staff, via huddles, regarding the Electro-Surgical Unit, Use of Policy. Specifically, regarding the review of the Surgeon's Preference Card prior to the start of the case. This ensures that the cautery devise is at the lowest level setting, as directed by the Surgeon.</p> <p>2. Educate staff, via huddles, regarding the process of confirming the power setting before activating use of the ESU.</p> <p>Auditing/Monitoring</p> <p>1. Audit OR cases with a level three fire risk to ensure that the power setting is confirmed before activating use of the ESU. Three months of data will be reported in Quality Council and Governing board. 100% compliance was met for October, November and December of 2015.</p> <p>Responsible Parties:</p> <p>OR Director, and Director of Quality Management</p>	<p>9/25/15</p> <p>9/25/15</p> <p>12/2015</p>

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	<p>because the patient wants it that way and it is doable."</p> <p>During a telephone interview with the Director of Surgical Services (DSS) on June 20, 2016, at 8:50 a.m., the DSS stated, "Special precautions are taken when a mask is used with facial surgery." She stated, "It is considered a Level Three fire risk which was the highest fire risk. This means supplemental oxygen, using a cautery and it is above the xiphoid process (smallest part of the breast bone)." The DSS stated, "We do a time out with all cases but the team discussed the high fire risk, and reminded everyone saline was on the Anesthesiologist's cart and the scrub technician had saline available.</p> <p>It is standard practice for the surgical team to perform a fire risk assessment before a surgery "to identify the 3 key elements that are necessary for a fire to start-the fire triangle". In the operating room, 3 key risks are:</p> <ul style="list-style-type: none"> (1) Surgical site or incision above the xiphoid; (2) Open oxygen source (receiving supplemental oxygen via face mask or nasal cannula); and, (3) An available ignition source (electro surgery unit, laser, or fiberoptic light source). <p>Each risk is given a score of 1. The scores are tabulated to determine a total fire risk score. (Reference: OR Manager Inc. January 2006 Vol.22 No.1 www.ormanager.com)</p> <p>According to documentation on the "Operating Room Nursing Document", a fire risk score of 3</p>			

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 CORONA REGIONAL MEDICAL CENTER

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	<p>points equaled "High" (suggesting all 3 components of the fire triangle for the operating room were present). The "[facility name] Operating Room Nursing Document" indicated, "General Comments: During time out fire score of 3 discussed with surgeon and anesthesia and that there was water on anesthesia cart. All agreed."</p> <p>The Anesthesia record dated August 26, 2015, indicated, "Oxygen at 5 liter a minute per face mask. The patient positioning at 11:40 a.m., oxygen by green mask. At 12:15 p.m., fire from closeness of the surgery to the airway and recognized immediately and oxygen shut off. Saline bottle poured on top of fire area and patient burnt skin and surgeon treating the fire injury with cooling measures and completed surgery and applied Silverdene ointment/cream (a sulfa based cream used on second and third degree burns to help prevent or treat serious infection) at the burnsite."</p> <p>The Narrative Note of Incident (fire in the OR) by the Anesthesiologist on August 26, 2015, at 1300, indicated, "Anesthesia given (MAC) and about to start procedure. Patient was moaning so additional Propofol (a medication used for sedation and anesthesia) given. Oxygen mask at 5 liters per minute. When surgeon started using the cautery, the operating room (OR) nurse noticed more than usual amount of smoke coming from the surgical area. Notification of surgeon and surgery tech noted burning of the scalp hair. Immediately saline poured on top of the head and face and oxygen supply cut off and we removed the drapes and checked for additional area of burn. The hair and scalp burn and</p>			

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	<p>left face (cheek) burn, eye lashes burn both sides, lower lid burn, left eye noticed back side and neck burn on left side and neck notice. First and second degree burns noticed per surgeon at this point. We continue with surgery without oxygen to avoid any further injury. Patient's vital signs were stable throughout the procedure and Silverdene cream applied to the face."</p> <p>The "Operative Report" completed by Surgeon A, dated August 26, 2015, indicated, the preoperative diagnosis for Patient A was lipoma, right forehead. The postoperative diagnosis indicated, "Lipoma, right forehead, first and second degree burn, left side of face and neck...Lipoma was identified and dissected combination of Bovie cautery (a medical device that cuts and seals [cauterizes] tissues and blood vessels by the way of a direct electrical current) and metzenbaum scissors (a type of surgical tool used to cut soft tissue) . During this portion of the procedure while cauterizing a vessel a spark occurred with ignition of the patient's hair. This was extinguished with gauze. Smoke was noted to be coming from under the drapes which were immediately pulled open. Burns were noted and drapes were completely removed. No active fires were noted under the drape. Moist laps were then placed over the patient's face and neck areas. There appeared to be a combination of both first and second degree burns involving the left side of the face and neck. There appeared to be no injury to the eyes. The patient was inspected for any other areas of injury. At this point, the burns were treated with Silverdene cream. The lipoma then removed using</p>			

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	<p>metzenbaum scissors and the incision closed ...At the end of the procedure, the patient was taken to recovery room in stable condition."</p> <p>The "Nursing Summary" dated August 26, 2015, indicated, " Complications: burns, eyebrows, eye lashes, left side of neck and face, left ear...Dressing: Silverdene cream applied to eyebrows, forehead, face, neck, and ear. Covered with wet gauze. Intraop Outcomes: Eyebrows gone, eyelashes gone, left side of face and neck burned, blister on left side of face and left ear."</p> <p>The Outpatient Progress Note/Discharge Summary dated August 26, 2015, indicated, " Complications: second and third degree burns, left forehead and left neck secondary to OR fire adjacent to left eye involves approximately 40 % of face. "</p> <p>The Perioperative Documentation dated August 26, 2015, at 18:55 p.m., indicated, " Pain Any Site Other Than Procedure Site: Yes; Pain or Soreness In Eyes: Yes; Lacerations, Injuries or Burns On Body: Yes; Post-anesthesia Complications: Other: Facial Burns; Neck; Patient Disposition: Other: (hospital name withheld), Mode of Departure: Ambulance.</p> <p>In an interview on August 27, 2015, at 3:25 p.m., the anesthesiologist stated, "The patient and surgeon wanted sedation and not general anesthesia. I used</p>			

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	<p>a mask and not a nasal cannula to administer oxygen since the patient was a large guy who may need more oxygen than a nasal cannula can deliver. If I am administering a small amount of oxygen (1-3 liters), I use a nasal cannula to administer the oxygen. The patient was receiving 4-5 liters of oxygen. The circulating nurse saw smoke from the</p> <p>cautery. She poured water on the face, pulled the drapes off, and called for help. The surgeon took the oxygen mask off the patient and I turned the oxygen off. I heard a sound and I did not see the spark." The anesthesiologist acknowledged he was responsible for the management of the medical gases.</p> <p>An interview was conducted with the DSS on August 27, 2015, at 3 p.m. The DSS stated, "They were using a mask and not a nasal cannula (a type of clear plastic tube that's used to deliver low concentrations of oxygen) for the administration of oxygen, and the Bovie was set at 35/35 and normally it should be set between 20-30 for a face."</p> <p>In a subsequent interview with the DSS on August 27, 2015, at 4:50 p.m., the DSS stated, "The circulating nurse plugs in the Bovie and sets the intensity level. It is our practice to check the preference cards prior to the surgery."</p> <p>An interview was conducted with the Circulating Nurse (CN) on August 27, 2015, at 3:38 p.m. The CN stated, "Before the incision was made I did a</p>			

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	<p>time out (final summary to accurately identify patient, surgical site, planned procedure). This surgery was a fire risk of three (highest risk). I told the team there was water on the pixis (automated drug dispensing machine) in case they needed it. All agreed with the time out. The patient started moving his arms after the incision was made. I retucked his arms, and anesthesia increased his medications. I went to the computer to chart and I heard drapes being ripped. I looked over and saw smoke coming from the patient. The OR Tech was dosing the patient with saline. I saw more smoke coming from the patient, and I ran over and pulled the drapes completely off the patient. The surgeon finished getting the lesion out and closed (the incision). He asked for Silverdene cream. I did not know his neck was burned until after the surgery. I knew his eyebrows and eyelashes were gone. When they turned the patient, they saw the burn on his neck, left shoulder, hair burned behind his left ear and down to the pillow."</p> <p>A second interview was conducted with the CN on August 27, 2015, at 5 p.m. She stated, "I plugged in the Bovie and it was set at 35/35. I did not set it at 35/35. It was already set at 35/35. I did not check the surgeon's preference card for his preferred settings."</p> <p>On August 27, 2015, at 4:20 p.m., the Scrub Tech was interviewed. He stated, "His (Patient A's) hair was singed, and the surgeon used a sponge to wipe it off. A few minutes later, I smelled smoke and saw a big flash. I grabbed the drapes and ripped them off, then I dosed him with water. The surgeon</p>			

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	<p>continued and the circulating nurse saw smoke, and dosed him again with water. A few minutes into the surgery, I told the surgeon the Bovie (electro-cautery unit) was set at 35/35 and I asked him if he wanted me to turn it down. I got no response from the surgeon. I don't know if he heard me or not. The left side of the patient's face, eyebrows and eyelashes were burned. His eyebrows were a grayish color and some redness by his eyes." The Scrub Tech also stated, the circulating nurse "plugs in the Bovie (electrocautery unit) and sets the intensity level."</p> <p>An interview was conducted with the Surgeon on August 27, 2015, at 4:40 p.m. The surgeon stated, "I made the incision, cauterized some vessels, and I noticed a spark and his hair was on fire. I patted it out with a sponge and took the drapes off. I did not see any actual fire and I did not see any more sparks. I smelled smoke after the spark and the circulating nurse came over and ripped the drapes off and poured more water on the patient. I did not use the Bovie anymore. Time out was done prior to the surgery and it was a fire safety level three. I don't recall anyone telling me what the Bovie setting was set at."</p> <p>Surgeon A's Preference Card for "Excision of Lesion" was reviewed on August 26, 2015. The preference card indicated a Bovie setting of 30/30.</p> <p>A subsequent telephone interview was conducted with the Director of Quality (DO) on February 2, 2016, at 2 p.m. The DO stated Patient A underwent skin graft surgery which required several follow up physician visits.</p>			

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	<p>A review of the facility's operating room policy and procedure titled, "Electro-Surgical Unit, Use of," policy issued March 2014, indicated, "Procedure: Set the ESU at the lowest level required to perform function as directed by the Doctor/Surgeon. Alert: Think of a fault in the circuitry any time the Surgeon continues to request a higher setting. Check all areas for problem points: patient dispersing pad, active electrode or ESU. Excessive power can increase tissue destruction and chance of burns." Section VI of this policy provides a reference to the "Association of Peri-Operative Registered Nurses (AORN) Standard Recommended Practice and Guides, 'Recommended Practices for Electrosurgery.'</p> <p>The "AORN Recommended Practices, Implementing AORN Recommended Practices for Electrosurgery" states, "Confirm the power setting with the operator before the ESU is activated and use the lowest setting to achieve the desired tissue effect...It is important to ensure that electro surgery (cautery) not be used in the presence of gastrointestinal gases or in an oxygen-enriched environment. Caution should be used when activating the active electrode near the head and neck region or in the presence of combustible anesthetic gases. The active electrode should be used as far away as possible from the oxygen source." (AORN Journal Article, March 2012, Volume 95, Number 3, pages 373-384.)</p> <p>The facility failed to follow their operating room</p>			

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NAME OF PROVIDER OR SUPPLIER CORONA REGIONAL MEDICAL CENTER-MAGNOLIA		STREET ADDRESS, CITY, STATE, ZIP CODE 800 S Main St, Corona, CA 92882-3420 RIVERSIDE COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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
	<p>policy and procedure as it relates to the use of the electrosurgical unit. The facility failed to check the surgeon's preference card in order to set the electrosurgical unit to the lowest level setting required to perform the surgical function, as directed by the surgeon.</p> <p>These failures are deficiencies that have caused, or are likely to cause serious injury and/or death to the patient, and therefore constitute an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.3.</p> <p>5</p> <p>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).</p>		<p>Policy and Procedure</p> <p>1. A process change was made to include the RN Staff confirming the power setting before activating use of the ESU, for cases with a level three fire risk. This ensures that the lowest level setting required for the surgery is used, as directed by the Surgeon.</p> <p>Education and Training</p> <p>1. Re-educate OR Staff, via huddles, regarding the Electro-Surgical Unit, Use of Policy. Specifically, regarding the review of the Surgeon's Preference Card prior to the start of the case. This ensures that the cautery devise is at the lowest level setting, as directed by the Surgeon.</p> <p>2. Educate staff, via huddles, regarding the process of confirming the power setting before activating use of the ESU.</p> <p>Auditing/Monitoring</p> <p>1. Audit OR cases with a level three fire risk to ensure that the power setting is confirmed before activating use of the ESU. Three months of data will be reported in Quality Council and Governing board. 100% compliance was met for October, November and December of 2015.</p> <p>Responsible Parties: OR Director, and Director of Quality Management</p>	<p>9/25/15</p> <p>9/25/15</p> <p>9/25/15</p> <p>12/2015</p>

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 RIVERSIDE COUNTY
 HEALTH & HUMAN SERVICES AGENCY