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
	050573	A. BUILDING _____ B. WING _____	11/02/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
EISENHOWER MEDICAL CENTER	39000 Bob Hope Dr, Rancho Mirage, CA 92270-3221 RIVERSIDE COUNTY

(X4)1D 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)	(XS) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00575944 - Substantiated Representing the Department of Public Health: Surveyor ID# 1977, 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(g): 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 1280.3(g) 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 & 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		Initial Comments Preparation and execution of this plan of correction does not constitute admission or agreement of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared and executed solely because it is required by federal/state law. POC Acceptable TBuchanan 12/6/18 2018 DEC -5 PM 2:15 RIVERSIDE CO DEPARTMENT	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Christine Johnstone TITLE: VICE PRESIDENT QUALITY & PROCESS IMPROVEMENT (X6) DATE: 12-5-18

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s). 1 thru 19*

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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	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 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. California Health and Safety Code, Section 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (2) Product or device events, including the following: (B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator. California Code of Regulations, Title 22, Division 5, Chapter 1, Article 6, Section 70413: Basic Emergency Medical Service, Physician on Duty, General Requirements: (a) Written policies and procedures shall be		California Code of Regulations Title 22, Division 5, Chapter 1, Article 6, Section 70413: Basic Emergency Medical Service, Physician on Duty, General Requirements	

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	developed and maintained by the person responsible for the service 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. California Code of Regulations, Title 22, Division 5, Chapter 1, Article 6, Section 70455. Comprehensive Medical Service Staff. (a) A full- time physician trained and experienced in emergency medical service shall have overall responsibility for the service. The physician or her or his designee shall be responsible for: (1) Implementation of established policies and procedures. (5) Assurance of continuing education for all emergency service staff including physicians, nurses, and personnel. Based on interview and record review, the facility failed to ensure synchronized cardioversion (shocking the heart) was performed correctly for one patient (Patient 1) in accordance with the facility policy and procedure and the manufacturer's instructions for use (IFUs) for the device. This failed practice resulted in Patient 1 suffering a cardiac arrest for 19 minutes, infiltration (leaking into the tissue) of caustic drugs used during the cardiac arrest into her hand, and loss of function in her right arm. Findings:		California Code of Regulations, Title 22, Division 5, Chapter 1, Article 6, Section 70455: Comprehensive Medical Service Staff. Eisenhower Medical Center (EMC) leadership, including the VP Medical Affairs, VP Patient Care/CNO, Medical Director/Emergency Department, Director Emergency Department, Graduate Medical Education (GME) Physician leadership, Professional Development Director, Risk Management Director, VP Quality and Process Improvement, Quality Improvement Director, and Quality Staff, met to review the Title-22 California Code of Regulations and the California Health and Safety Code named within this document. Leadership also reviewed the EMC Policy, "Defibrillator – Pacer, External", effective at the time of the incident. The policy and procedures	11/30/18 12/4/18

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	On February 28, 2018, the Department received a complaint from Patient 1, which resulted in the initiation of an investigation on March 19, 2018. During an interview with Patient 1 on March 19, 2018, at 3 p.m., Patient 1 stated she had a history of a rapid irregular heartbeat that at times required a cardioversion procedure to help her heart return to a normal heart rhythm. She stated she went to the Emergency Department (ED) on July 20, 2017, experiencing a rapid, irregular heart rhythm. Patient 1 stated she received medications to try to convert (change back to a normal) the abnormal heart rhythm, but the medications did not work. She stated the ED physician decided to perform synchronized cardioversion. Patient 1 stated she went into a cardiac arrest (when the heart stops beating) during the procedure, and when she woke up, she had a breathing tube in her throat and was on a ventilator (breathing machine). Patient 1 stated during her hospital admission, she experienced severe pain in her right hand, and her hand started "turning black". Patient 1 stated she was taken for emergency surgery on her hand, and was told by the surgeon that her hand may have to be amputated. According to Patient 1, she returned for multiple surgical procedures on her hand and arm, and now "It is all cut up and scarred and does not work correctly". Patient 1 stated the cardiologist told her during the cardioversion procedure, the machine fired on the t-wave, meaning the sync button had not		in place at the time of the patient experience reflect EMC's standard of best practices, evidence-based patient care, and the guidelines and recommendations of the American Heart Association (AHA). As a provider of Graduate Medical Education (GME), Eisenhower Medical Center is committed to clinical excellence in residency and fellowship education. Through our affiliation with the Accreditation Council for Graduate Medical Education (ACGME), EMC is an accredited institution for our Internal Medicine and Family Medicine residency programs, and a Sports Medicine fellowship. Further, The Association of American Colleges (AAMC) has granted EMC with membership into the Council of Teaching Hospitals and Health Systems (COTH). Patient 1 is a 51 year old female with a medical history of atrial fibrillation, morbid obesity, pulmonary hypertension, premature ventricular contractions of the heart, Crohn's disease, short bowel syndrome, gout, multiple dilatations for ileocecal stricture, pneumonitis with chronic steroid use, and multiple complex cardioversions.	

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	been pushed (causing her to experience a cardiac arrest). According to the American Heart Association's (AHA) Advanced Cardiac Life Support Guidelines 2018, synchronized cardioversion delivers a low energy shock that uses a sensor to deliver electricity, which is timed or synchronized to be delivered at a specific point in the QRS complex (heartbeat on the monitor. When the synch button is pushed, the machine waits for and detects the "R" wave, then fires on the "R" wave in an attempt to convert an abnormal heart rhythm to a normal rhythm. A synchronized shock is delivered at this precise moment to avoid causing or inducing cardiac arrest. If the synch button is not pushed, the machine fires immediately, increasing the risk of firing on the "T" wave (known as the vulnerable period) and inducing cardiac arrest. During an interview with the Director of Quality (DQ) on March 21, 2018, at 11:05 a.m., the DQ stated she received a call from Patient 1, and the patient told her about concerns she had while she was a patient at the facility. The DQ stated Patient 1 told her the cardiac defibrillator machine was not used correctly during a synchronized cardioversion procedure, the machine fired on the t-wave, and she		Patient 1, who has an ongoing and established relationship for medical care with EMC, has had multiple visits to the Emergency Department (ED) for her atrial fibrillation, and for which she had previously received synchronized cardioversion treatment. External synchronized cardioversion is a procedure that is often performed in the ED for patients experiencing serious cardiac rhythms. Patient 1's care at EMC for atrial fibrillation has included at least nine synchronized cardioversion procedures prior to July 20, 2017, followed by six cardioversion procedures since then, the most recent cardioversion occurring on November 23, 2018. In most cases, the synchronized cardioversion procedures for Patient 1 were provided in the EMC ED. On the morning of July 20, 2017, Patient 1 was examined in the EMC ED with a diagnosis of atrial fibrillation. While in the ED, the patient was recommended to have medication therapy for her diagnosis of atrial fibrillation until she could be seen by her cardiologist. The patient	2013 To 2018 7/20/17 7/20/17

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	went into cardiac arrest. The DQ stated during the facility's investigation, the medical staff determined the only way the machine would have fired on the t-wave was if the sync button was not pushed. During an interview with the Quality Nurse (QN) on March 21, 2018, at 11:30 a.m., the QN stated during the investigation, the facility determined the residents (licensed physicians still in training) needed to be educated to push the, "sync," button every time they were performing synchronized cardioversion, as they did not all know the machine would revert back to the unsynchronized mode after each shock. During an interview with the ED attending physician (EDMD) on April 6, 2018, at 1:50 p.m., the EDMD stated she was present at the bedside during the cardioversion procedure on Patient 1. The EDMD stated Resident 1 kept asking if he could, "push the shock button," so she, "Thought," it was Resident 1 who pushed it. The EDMD stated she did not know if Resident 1 pushed the synch button before shocking Patient 1, but she saw it fire on the T-wave, and Patient 1 "immediately" went into cardiac arrest. During an interview with the ED Registered Nurse (EDRN) on June 19, 2018, at 6:30 a.m., the EDRN stated he was present during the cardioversion procedure on Patient 1. The EDRN stated Resident 1 was the one performing the cardioversion procedure, while he (the RN) was doing the charting. The EDRN stated after the fourth shock, Patient 1 went into cardiac arrest. The EDRN stated he did		instead requested that electric synchronized cardioversion be performed in the ED as she has been under the care of cardiologists whose treatment plan includes cardioversion as the primary treatment due to ineffective results with medications. The patient underwent attempts at cardioversion by staff trained in Advanced Cardiac Life Support (ACLS). ACLS is specialized training from the American Heart Association and is a requirement of all staff performing synchronized cardioversion. All physicians, including residents, and ED Registered Nurses are educated and maintain current certification in the American Heart Association ACLS program which includes how to perform high quality cardiopulmonary resuscitation (CPR) and synchronized cardioversion. On January 16, 2018, Patient 1 called the EMC patient safety/risk hotline and spoke with the Director of Quality (DQ) about an experience in the ED on July 20, 2017. Specifically, Patient 1 wanted to know if EMC staff received training in Advanced Cardiovascular Life Support (ACLS) and if the synchronization button was activated during the cardioversion procedure that occurred at that time.	7/20/17 7/20/17 1/16/18

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	not know if Resident 1 pushed the synch button before the fourth shock. The EDRN stated he reminded Resident 1to push the synch button before the first three shocks, but not before the fourth shock because, "I was charting." The EDRN stated he found out "later" that "maybe," Resident 1 had not pushed the synch button. During a concurrent interview with the Associate Graduate Medical Education Program Director - (APO), and Resident 1, on June 19, 2018, at 2 p.m., the APO stated one of two things would cause the machine to fire on the t-wave, either the synch button was not pushed, or the equipment failed to function properly. The APO stated, "It had to be one of those two things." Resident 1 stated he was not aware the synch button had to be pushed every time for a cardioversion, "at that time in my training." Resident 1 stated he was manning the machine and pushing the shock button, he was, "not sure," if he pushed the synch button, and, "somebody else may have pushed it." Resident 1 stated he did not verify the machine was sensing the R-wave before pushing the shock button. During an interview with the ICU RN on June 20, 2018, at 2:30 p.m., the ICU RN stated she received Patient 1 on July 21,2107, at 7 a.m. The ICU RN stated she was told in report Patient 1 "coded (cardiac arrest)," in the ED, her IV infiltrated, and they were watching her hand for possible		Patient 1's questions were reviewed by executive leadership and the quality team and a thorough investigation using the root cause analysis process was conducted, including a review of Patient 1's medical record for that visit, interviews with staff involved in the Patient 1's care, and review of the current ACLS training program. The investigation confirmed that ED staff follow evidence based guidelines for cardioversion procedures to provide synchronized cardioversion shock delivery that is timed with the QRS complex to avoid shock delivery during the T wave. The investigation found that Patient1 received three synchronized shocks with no conversion to a stable heart rhythm. However, there is documentation that the fourth cardioversion shock was released on the T wave, resulting in ventricular fibrillation followed by cardiac arrest with successful resuscitation. The results of the investigation were shared with Patient 1 in writing and during a follow up telephone call from the DQ on February 15, 2018.	1/16/18 To 2/14/18 1/16/18 To 2/14/18 1/16/18 To 2/14/18 2/15/18

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	compartment syndrome (severe pressure from damaged or swollen tissue causing pressure and loss of blood flow to the affected areas). The ICU RN stated Surgeon 1 explained to Patient 1 the surgery would be, "very difficult," and could possibly result in amputation. The ICU RN stated Patient 1was, "emotionally terrified," and requested chaplain services to come and pray with her. A review of Patient 1's medical record was conducted on March 21, 2018. The record indicated Patient 1, a 52-year-old female, presented to the ED on July 20, 2017, in atrial fibrillation with a rapid ventricular response (a rapid, irregular heart rhythm). The record indicated Patient 1 consented to undergo synchronized cardioversion. The ED nurse's notes indicated on July 20, 2017, synchronized cardioversion was performed by Resident 1 at 11:13 p.m., again at 11:14 p.m., again at 11:15 p.m. The record indicated at 11:17 p.m., Patient 1's heart stopped beating, and a code blue was called. (Code blue is an emergency situation announced in a hospital in which a patient is in cardiac arrest (heart stops beating), requiring a team of providers sometimes called a 'code team' to rush to the specific location and begin immediate life sustaining efforts). Patient 1was intubated (a breathing tube was inserted into her throat) and she was placed on a ventilator (a breathing machine).		The ED attending physician had performed many successful cardioversion procedures and the team assisting the physician followed a detailed work process consisting of clearly defined steps, which included performing a thorough "time out" before beginning to administer the first shock. Patient 1 was prepared for the procedure and the defibrillator was set in synchronization (sync) mode before each shock for the first three shocks. The defibrillator is designed to automatically revert back to non-synchronized mode after each shock is delivered. It was noted by the physician that the fourth shock resulted in the delivery of a non-synchronized shock delivered on the T wave resulting in ventricular fibrillation, cardiac arrest, and resuscitation. In the investigation that was conducted, it remains unclear whether Resident 1, who participated in the cardioversion, re-activated the synchronization mode prior to the fourth shock to Patient 1.	7/20/17 7/20/17 7/21/17 1/16/18 To 2/14/18 7/20/17

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	The code blue record indicated Patient 1's heart returned to a normal rhythm 19 minutes later or at 11:36 p.m. During the code blue, Patient 1 received three additional shocks, and the following medications: two milligrams (mg) of epinephrine intravenous (IV meaning directly into the vein), 300 mg of amiodarone IV, and one gram of calcium chloride IV. Epinephrine is a medication classified as a vesicant, (a medication that causes ischemia (death) to tissue if it infiltrates or leaks out of the vein, and into the surrounding tissues). Calcium chloride is a medication also classified as a vesicant which causes destruction to tissues, if it leaks into surrounding tissues. Further review of the ED nurse's notes indicated the following: On July 21, 2017, at 1:46 a.m., Patient 1 was extubated (the breathing tube was removed), and she was complaining of pain to her right hand. Her hand was noted to be dusky in color; At 2:17 a.m., Patient 1's right hand was increasingly cyanotic (turning bluish/purple), and the physician was at the bedside; At 3:05 a.m., Patient 1's right hand was, "still discolored purple," with a capillary refill time of greater than three seconds (indicating decreased blood flow to the hand). Warm compresses to be		Insertion of an intravenous (IV) catheter into a vein was one of the required steps in preparing Patient1 for the cardioversion procedure. The IV provides access for solutions and medications to be administered during the cardioversion and is crucial for administering life-saving medications during cardiopulmonary resuscitation (CPR) such as Epinephrine and Calcium Chloride. Even when closely monitored, an IV catheter may result in extravasation, where solutions and medications flow into surrounding tissue spaces during IV infusion and cause damage that may extend to involve nerves, tendons, and joints. Patient 1 was also on anticoagulants, medications that act to thin the blood, which may increase the risk of extravasation or cause a compartmental injury by increasing local bleeding. Treatment is determined by the stage of extravasation, the nature of the infiltrating solution, and the availability of specific antidotes (medications that can help to reverse some of the effects of extravasation.)	7/20/17 7/20/17

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	applied to the right hand in response to a physician's order. Patient 1 was admitted to the Intensive Care Unit (ICU). The ICU nurse's notes dated July 21, 2017, indicated the following: At 4 a.m., Patient 1's right hand was cyanotic/purple and cold to touch, with slow capillary refill and, "severe," edema (swelling). Patient 1 had a decrease in sensation (feeling) to her right hand, and was unable to perform fine motor movements. Physicians were at the bedside and aware: At 5 a.m., Patient 1's right hand was still cyanotic/purple and cold to touch, and the physicias were aware; At 6 a.m., Patient 1's right hand was still cyanotic/purple and cold to touch, with slow capillary refill; At 7:30 a.m., Patient 1's right hand was purple/mottled, with slow capillary refill time, pain, and numbness and tingling in her hand; At 7:34 a.m., Patient 1's physician spoke with an orthopedic surgeon regarding, "emergent surgery;" At 7:43 a.m., Surgeon 1 was at Patient 1's bedside consulting for surgery; At 7:45 a.m., Patient 1's right hand remained purple/mottled, with slow capillary refill, pain,		Intubation, whereby a patient requires a temporary breathing tube, can occur as a life-saving measure during a Code Blue emergency. Patient 1 required the assistance of intubation to assist her breathing for approximately an hour while in the ED. Often, restlessness occurs and patients will unknowingly pull at tubes and lines, such as an endotracheal tube used for intubation. The patient's plan of care included measures meant to protect and secure the Patient 1's IV lines and endotracheal tube while physicians and staff could be assured that the endotracheal tube could be removed safely and Patient 1 could breathe comfortably on her own. Patient 1 had an IV located in the right hand for receiving medications in the ED. Upon arrival to the ICU accompanied by the ED physician and ED Registered Nurse, the patient's right hand was noted to be swollen and reddened. Patient 1 complained of severe pain in her right hand. The patient's nurse immediately notified physicians of the condition of the patient's right hand.	7/20/17 7/20/17 7/21/17 7/21/17 7/21/17

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	numbness and tingling, and a weak grip. At 8:05 a.m., Patient 1's right hand remained purple/mottled, with slow capillary refill, severe edema, pain, numbness, and tingling. Chaplain services were provided as the patient requested them "for prayers;" At 8:15 a.m., Patient 1's hand remained purple/mottled, with slow capillary refill, pain, and numbness: At 8:30 a.m., Patient 1's hand remained purple/mottled, with slow capillary refill, pain, numbness, and tingling: At 8:45 a.m., Patient 1's right hand remained purple/mottled, with slow capillary refill, decreased sensation, pain, numbness, and tingling: At 9 a.m., Patient 1's right remained purple/mottled, with slow capillary refill: At 9:15 a.m., Patient 1's right hand remained purple/mottled, with slow capillary refill. Patient 1 continued to have pain, numbness, and tingling, with no sensation on the middle finger or the top of the hand. The surgeon was aware of the changes; and, At 9:30 a.m., Patient 1's hand remained purple/mottled, with slow capillary refill, pain, numbness, and a "very limited" grasp with her right hand. The Physician Progress Note dated July 21, 2017,		Once the signs of extravasation were detected, the physician considered treatment options for Patient 1. One option could have been Regitine, a medication used to treat certain extravasations; however, this medication was not available to hospitals due to a national shortage. As an alternative to Regitine, evidence-based emergency management was started including the application of nitroglycerin paste and warm compresses to the skin on the right hand to mitigate the effects of IV medications that could have infiltrated into Patient 1's hand. Nursing continued to medicate Patient 1 for her hand discomfort, apply warm compresses, document the condition of her hand, and communicate any physical changes to the physicians. EMC readily provides chaplaincy care and services for all patients. It is documented in the patient's medical record that upon request the nurse arranged for the chaplain to visit with the patient prior to surgery.	7/21/17 7/21/17 7/21/17 7/21/17 7/21/17

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	indicated, "The post ROSC (return of spontaneous circulation) period was complicated with the finding of the right hand pain, swelling, cyanosis/redness, decrease in sensation and motor dysfunction. Patient was first seen in the ICU around 7:30 a.m. by our team. Dr. [name], vascular surgeon was notified immediately. Pt (patient) was found to have the whole hand sensory and motor deficit. ...Dr. [Surgeon 1] was notified immediately for concern of right hand compartment syndrome. [Patient 1] went to OR immediately to decompress the involved compartments." The operating room (OR) nurse's notes indicated Patient 1 was taken to surgery on July 21, 2017, at 9:39 a.m. The Operative Report dated July 21, 2017, indicated the following: 1. Preoperative diagnoses included status post cardiac arrest with vascular insult to the right hand and right forearm; 2. "Due to the emergent nature of the evolving compartment syndrome, the patient was brought back to the operating room; and, 3. Surgeon 1 performed the following procedures on Patient 1 on July 21, 2017: a. Right hand compartmental release;		The vascular surgeon performing the surgery on July 21, 2017 for compartment syndrome treatment informed the patient of the risks, benefits, and alternatives of the surgery to provide the patient with operative and non-operative management information. This counseling included known potential complications as a result of surgery. Due to the early recognition of the extravasation leading to compartment syndrome, the patient was able to have the recommended emergent surgery to prevent permanent injury to her hand.	7/21/17 7/21/17

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	b. Right carpal tunnel release; c. Right dorsal forearm fasciotomy; d. Right volar compartment fasciotomy ; and, e. Application of a wound vac sponge to the right upper extremity. (Multiple incisions on the right hand and wrist and along the top and bottom of the right forearm , to allow room for swollen tissue to expand and relieve tissue-damaging pressure, followed by placement of a drain (wound vac) to promote wound healing). Wound vac is a vacuum-assisted closure of a wound and is a type of therapy to help wounds heal. During the treatment, a device decreases air pressure on the wound. The Cardiology Inpatient Progress Note dated July 22, 2017, indicated, "She (Patient 1) underwent electrical cardioversion multiple times and on her 4th shock she went into ventricular fibrillation (cardiac arrest). During the 4th shock, she was shocked on the T-wave. Today she is status post-surgery on her right hand and decompression of compartment syndrome. During the code blue, her IV became infiltrated and appears that the epinephrine was infiltrated into the right hand which caused compartment syndrome." The Operative Report dated July 23, 2017 (two days		On July 23, 2017, Patient 1 had a planned return to surgery for right hand irrigation and debridement of the surgical wounds, and placement of a wound VAC to accelerate the natural healing process of the wound bed. Also planned was the return to surgery on July 27, 2017 once swelling had reduced and the tissue had improved enough to allow closure of some of the wounds. Planned wound intervention continued throughout the patient's stay at EMC according to clinical wound management standards and based on the steady improvement of the patient's tissue. As of July 19, 2018, the vascular surgeon documents that overall Patient 1's function of her right hand, forearm, and elbow is excellent. Patient 1 has had complete healing of the incisional wounds, and has met long term occupational health goals of therapy.	7/23/17 7/27/17 7/27/17 To 8/8/17 7/19/18

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	after the initial surgery), indicated Patient 1 returned to the OR for additional surgical intervention. The report indicated Surgeon 1 performed irrigation and debridement (I & D - flushing and removal of dead tissue) on the wounds throughout the right hand and forearm. The wounds were measured as follows: Forearm #1 - 18X 5 X 1 cm (centimeters) (7 X 2 X 0.5 inches); Forearm #2 - 4 X 4 X 1 cm (1.5 X 1.5 X 0.4 inches); Forearm #3 - 25 X 8 X 2 cm (9.8 X 3 X 0.8 inches); Hand #1 - 6 X 1X 1 cm (2.4 X 0.4 X 0.4 inches); Hand #2 - 6 X 2 X 1 cm (2.4 X 0.8 X 0.4 inches); and, Hand #3 - 4 X 0.5 X 0.5 cm (1.5 X 0.2 X 0.2 inches). The Operative Report dated July 26, 2017 (three days later) indicated Patient 1 returned to the OR for additional surgical intervention. The repprt indicated Surgeon 1 performed further I&D of the wounds, partial closure of two of the wounds, and full closure of one of the wounds. Occupational Therapy Progress notes indicated the following: 1. On August 1, 2017, Patient 1's primary concern was carrying out activities of daily living due to impaired function and Pain in her arm. Patient 1 stated, "Will I ever get full range (of motion) again?"		EMC takes patient safety and quality of care very seriously. In response to this patient outcome, EMC took certain steps to promote appropriate risk re-education strategies, which were implemented in an effort to prevent recurrence of a non-synchronized shock during cardioversion. <u>Corrective Actions:</u> To ensure the reliability of high performance team dynamics and communication for cardioversions performed in the ED an effective call-out process now occurs prior to the administration of each shock to confirm that the defibrillator is in synchronization mode. A label has been placed on the defibrillator equipment to call attention to the need to re-set the synchronization mode after each shock during a cardioversion. ED physicians, including residents, and ED registered nurses participated in re-education via mandatory staff meeting, email, and computer based learning module, to be aware of what mode the defibrillator remains in or reverts to following activation.	11/30/18 and Ongoing 11/30/18 and Ongoing 11/30/18 and Ongoing 11/8/18, 11/9/18 12/3/18 and Ongoing

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	The goals for patient 1 were to teach her to use her left hand to squeeze her toothpaste, brush her teeth, and rinse and wash her face; and, 2. On August 2, 2017, Patient 1 stated she had a, "T-Rex," arm and couldn't rec;ich to clean herself. She stated she was going to have to get an, "adaptive aid." The Operative Report dated August 3, 2017 (eight days later) indicated Patient 1 returned to the OR for a fourth surgical intervention. The report indicated Surgeon 1 performed I& D of a right hand wound, and closure of two of the wounds. The wound care notes dated August 8, 2017, indicated Patient 1was being prepared for discharge from the facility with the following wounds and wound care plan: 1. An open wound on the posterior (bottom) side of the right forearm near the wrist measuring 1O cm long X 5.5 cm wide X 0.7 cm deep (4 X 2.2 X 0.3 inches). The area around the wound was edematous and painful, with a pain level of 5/10. A picture of the wound revealed muscle and tendon were exposed. A wound vac was in place to promote wound healing, and the exposed areas were covered with dressings; 2. An open wound on the anterior (top) aspect of the right hand measuring 8 cm long X 5 cm wide X 0.8 cm deep (3 X 2 X 0.3 inches). A picture of the wound revealed it was open, and raw tissue was exposed. The wound had pink pale tissue exposed,		Initial resident orientation now requires completion of a competency in the operation of the cardioversion machine and includes setting to synchronization mode prior to delivery of each shock. Monthly resident mock code simulation has always been included in resident education and is ongoing. To supplement the existing ACLS and mock code education, an emphasis on synchronization for supraventricular tachycardia heart rhythms has been added and requires periodic return demonstration of mock cardioversion with synchronization. <u>Compliance and Monitoring:</u> Random direct observations of cardioversion procedures in the ED will be conducted to monitor for 100% completion of time outs performed prior to each shock delivered during cardioversion. Monitoring will occur for three months to achieve 100% compliance and will be re-evaluated as needed.	12/3/18 and Ongoing 12/3/18 and Ongoing 12/4/18 and Ongoing

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	was edematous, and had serosanguinous (pink fluid} drainage. The wound was covered with dressings; 3. Multiple dark sutures along the anterior and posterior aspect of the arm and the palm of the hand. The sutures were intact; and, 4. Patient 1would receive continued surgical wound care from a home health nurse. Nurse's notes dated August 8, 2017, at 3:04 p.m., indicated Patient 1 was discharged home with a portable wound vac, discharge instructions, and prescriptions. During a follow-up interview with Patient 1 on June 19,2018, at 2:40 p.m., Patient 1stated she completed physical therapy in April 2018 (eight months after her injury). Patient 1 stated her right arm was "very scarred." Patient 1 stated she had difficulty grasping and holding on to items, and she, "frequently ," dropped things. Patient 1 stated she was "still" having pain, and some days were "worse than others." The facility policy titled, Defibrillator - Pacer, External," was reviewed on August 15,2018. The policy indicated the following: When performing synchronized cardioversion: a. Press the SYNC on/off softkey; b. The sync marker [an arrow] would appear on the		GME Leadership, or their designee, will monitor that 100% initial competencies for cardioversion, cardioversion time-out, and synchronization of the cardioversion machine are completed as part of new resident orientation. Monitoring will occur for each new resident orientation and be re-evaluated as needed. Responsible Person(s): Medical Director, Emergency Department Director and Program Director, Graduate Medical Education Vice President Patient Care Services/Chief Nursing Officer	12/4/18 and Ongoing

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	monitor above each detected R-wave; c. Verify the markers are clearly visible on the monitor and their location is appropriately consistent from beat to beat. If necessary, use the LEAD and SIZE buttons to yield the best display; d. A "SYNC XXXJ SEL" message appears on the display; e. Press the CHARGE button on the monitor; f. Press and hold the SHOCK button until the energy is delivered to the patient; and, g. The defibrillator will automatically default back into defibrillation mode. For additional synchronized cardioversion, press the SYNC on/off softkey. A review of the manufacturer's IFUs titled, "R series(r) ALS Operator's Guide," issued December 2013, indicated the following: a. "Only skilled personnel trained in Advanced Cardiac Life Support and familiar with equipment operation should perform synchronized cardioversion;" b. Certain arrhythmias require synchronizing the defibrillator with the R-wave to avoid induction of ventricular fibrillation (cardiac arrest). In this case, a sync circuit within the defibrillator detects the patient's R-wave. When the shock button is pressed and held, the unit discharges with the next detected R-wave, thus avoiding the vulnerable T-wave			

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	segment of the cardiac cycle; c. Markers above the R-wave indicate the R-wave is being detected. "Verify the markers are clearly visible on the monitor and their location is appropriate and consistent from beat to beat;" d. "Unless otherwise configured, the unit automatically exits synch mode after each shock and when the mode selector is moved to monitor, pacer, or off; e."To reactivate sync mode, press the sync on/off softkey again;" f."WARNING! Verify the EKG waveform is stable and that a Synch marker appears only with R-waves. If synch markers are not present on the remote device display, or do not appear to be nearly simultaneous with each R-wave, do not proceed with synchronized cardioversion:" and, g. "A lethal arrhythmia may be induced through improper synchronization." The facility failed to ensure a defibrillator was used in accordance with their policy, procedure, and the manufacturer's instructions. This failure caused Patient 1 to sustain cardiac arrest, infiltration of medications into the patients' hand/arm resulting in compartment syndrome, a prolonged hospital stay, multiple surgical procedures, and loss of function in her right arm. These failures are deficiencies that have caused, or			

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	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. 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).			