CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

CA DEPT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050055	A. BUILDING _____ B. WING _____ MAY 16 2012	06/24/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CALIFORNIA PACIFIC MEDICAL CENTER – ST. LUKE'S CAMPUS HOSPITAL	3555 Cesar Chavez, San Francisco, Ca 94110-4403 SAN FRANCISCO COUNTY

L&C DIVISION
SAN FRANCISCO

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00272808 - Substantiated Representing the Department of Public Health: Surveyor ID # 26616, 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. Health and Safety Code Section 1279.1(b)(1)(D) (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained. T22 DIV5 CH1 ART3-70223(b) (2) Surgical Service General Requirements (b) A committee of the medical staff shall be		**Please Note:** The following constitutes California Pacific Medical Center (CPMC) - St. Luke's Campus Hospital's credible evidence of correction of the alleged deficiencies cited by the California Department of Public health in the Statement of Deficiencies Form CMS-2567 dated 6/24/11. Preparation and /or execution of this credible evidence does not constitute admission of agreement by the provider of the truth of the fact alleged or the conclusions set forth in the Statement of Deficiencies. **Corrective Action:** 1. The central line insertion process was changed to include post-procedure communication and documentation to account for the removal of the guidewire / introducer used in the procedure. CPMC providers use a Central Line Procedure Checklist. The Checklist was revised to include a space for documenting the removal of the guidewire / introducer. A copy of the checklist is attached. **Monitoring Process:** The Central Line Insertion Checklist is used to provide documentation of all components of the insertion procedure. A form is completed for every central line insertion in order to be sure that all processes related to central line placement are executed with each line placement.	7/1/11 7/20/11 ongoing

Event ID:6BX411 4/20/2012 10:06:46AM

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Steven Cherry — Director, Risk Management — May 14, 2012

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5/16/12 A. Thomas R/HFEN

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	Continued From page 1 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. This regulation was not met as evidenced by: Patient 1 was admitted to the Emergency Department on [redacted]/11 with diagnoses including diabetic ketoacidosis (serious complication of diabetes that occurs when there's little insulin and the body breaks down fats producing acids called ketones) acute kidney failure, and lactic acidosis (an acid produced by muscle cells and red blood cells that build up in the bloodstream faster than it can be removed). The [redacted]11 emergency room (ER) Admission notes indicated Patient 1 needed an emergency dialysis due to possible kidney failure and lactic acidosis. The doctor wrote, "... A Hemacath (catheter used for hemodialysis) was inserted in the right femoral (right groin)... A guide-wire was inserted and a dilator was used and the catheter was inserted with about 10 ml. of blood loss without complications. All ports were flushed after good aspiration and smooth flow of blood. This was sutured in placed and dressed without complication....The		Copies of all completed Central Line Insertion Checklist and Procedure Note forms are forwarded to the Quality department. The forms are reviewed to confirm the line insertion process was followed and the guidewire / introducer was removed. **Responsible Person:** Director, Risk Management **Corrective Action:** 2. The Emergency Department is staffed by experienced Emergency Department physicians however; the group has limited experience in placing catheters used for dialysis access. There was an in-service presentation and discussion at the Emergency Department physician meeting. Additional training on the use of the dialysis vascular access kit was provided to the ED physicians. **Monitoring Process:** Placement of a dialysis vascular assess catheter is a low volume procedure for the Emergency Department. Each time the procedure is performed, it will be reviewed by the ED physician group. **Responsible Person:** Medical Director, Emergency Department	quarterly 6/15/11 June 2011 and ongoing

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patient was admitted to the ICU (Intensive Care Unit), ...to have emergent dialysis..."

The [redacted]11 intensive care unit (ICU) doctor History and Physical Examination notes indicated, "Bradycardic arrest (heartbeat drops below 50 beats/minute) during HD (hemodialysis). He responded to epinephrine (medication to increase heart rate) and bicarbonate (medication to neutralize too much acid in the blood)."

The [redacted]11 Pulmonary Critical Care Consultation indicated, under History of Present Illness "...Upon arrival to the ICU, it was noted that he was very tachypneic (rapid breathing), had altered mental status, had bradycardic arrest (arrhythmia or abnormally slow heartbeat less than 50 beats per minute) short CPR (cardiopulmonary resuscitation), apparently difficult intubation...." Under section Studies: "...Chest x-ray post intubation... also noted that he had something that looked like a guide wire at the level of his right ventricle (right lower chamber of heart) and extending up to the superior vena cava (large vein that carries blood from the upper part of the body to the right side of the heart) and that was confirmed twice on the chest x-ray" Under section Plan: # 10. Of note, possibility of retained wire will be addressed and patient may need interventional radiology procedure to "fish it out"....

Review of the manufacturer's Hemo-Cath

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Instructions for Use indicated, "...Read instructions carefully before using this device....Caution: The length of the wire inserted is determined by the size of the patient....Cardiac arrythmias (heart rhythm which could be abnormally rapid or abnormally slow) may result if guidewire is allowed to pass the right atrium (right upper chamber of heart)."

The Hemo-Cath guidewire was inserted from the right femoral vein in which the guide-wire could have traveled in the direction of the blood flow from femoral vein to the heart where the catheter lodged and was seen on the chest X-Ray. This occurrence had the potential to cause the bradycardic arrest (a cardiac arrythmia) when the guide-wire passed the right atrium (upper chamber of heart) going thru the right ventricle (right lower chamber) as the Hemo-Cath instruction for use indicated, "Caution: Cardiac arrythmias may result if guidewire is allowed to pass the right atrium."

The [redacted]/11 Radiology Consultation Report indicated, "Emergency consent obtained. I was asked by Dr. ... to perform emergent guidewire retrieval from the vena cava. Patient transferred emergently from St. Luke's Hospital. Skin anesthetized with 1% Lidocaine solution. Indwelling right femoral venous catheter removed and exchanged with a French sheath. Using a 15 mm (millimeter) loop snare, the indwelling guide-wire was then removed in its entirety with careful observation

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of the guide-wire as it traverses the right atrium (right upper chamber of heart). Guidewire removed in its entirety. Guidewire sent for appropriate pathologic analysis. Indwelling sheath removed and replaced with vas (vascular) catheter. Vas catheter sutured in place."

During a concurrent observation and interview on 6/24/11 at 4:45 PM, Dr. A stated Patient 1 was seen by another doctor in the ER and he recommended a Hemacath so the patient could have an emergency dialysis. He said that he had placed dialysis access before but when he looked at the Hemo-Cath kit in the ER, he said, "I wasn't familiar of the Hemo-Cath kit because it was not the usual kit that I used but when I opened the kit and saw that the only difference was the Vascu-Sheath (type of dilator with sheath or covering), I thought I knew how to use it." When he was asked if he had read the Hemo-Cath instructions for use, he said, "The kit does not come with instructions but the insertion procedure and technique would be the same for all catheters, so I really thought I could use the Hemo-Cath." He was asked to describe and demonstrate the procedure he used on how he inserted the Hemo-Cath to Patient 1. He opened the Hemo-Cath kit and using the contents of the kit, he described and demonstrated the procedure as follows:

1. He prepped, draped and anesthetized the site on the right groin, he inserted the introducer needle to the site, thread the

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	Continued From page 5 guide-wire in to the needle and advanced the guidewire (27.5 inches length) about 1/2 to 2/3's of the length of the wire then removed the introducer needle while securely holding the guidewire on his left hand. 2. He took the scalpel, made a slit in to the skin site and thread the 12F Dilator and the 13F Vascu-sheath into the guidewire and dilated the vein. 3. He removed the 12F Dilator and left the 13F Vascu-Sheath and the guidewire inside the vein. 4. He took the double lumen catheter, thread it into the guide-wire and the 13F Vascu-Sheath. During the observation on 6/24/11, as soon as Dr. A finished threading the double lumen catheter into the guide-wire and the 13F Vascu-Sheath, he let go of the guide-wire, and the guide-wire was no longer visible. The only thing he was holding securely was the catheter. At this point, he was stopped in continuing his demonstration and was asked if he could see how he let go of the guidewire and lost sight of it during the procedure. He said, "Yes". He added that at the time of the procedure, he did not realize that the guidewire was inside the catheter and 13F Vascu-Sheath, because he was focused on the Vascu-Sheath being left in place with the catheter. He said he realized the catheter won't work with the Vascu-Sheath in and after realizing that, he said he had no			

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other option but to remove the catheter and place a new one. He opened another vascular kit (a different kit from Hemo-Cath) and inserted another guidewire into the site. He was asked if he checked where was the first guidewire he used, he said, "I looked for it but I thought I dropped it on the floor when I removed the 13F Vascu-Sheath and the double lumen catheter. I did not think it was inside the patient until they told me that the guidewire was seen on the X-ray."

Review of the manufacturer's Hemo-Cath Instruction For Use indicated, "...Read instructions carefully before using this device.... Caution: ... The guidewire should be held securely during this procedure....Once proper placement is confirmed, remove guidewire and stylet and close the clamp...."

An article from Nothing Left Behind: A National Surgical Patient-Project to Prevent Retained Surgical Items (an educational site intended for use by the healthcare organization to prevent retained surgical item at http://nothingleftbehind.org/Instruments.html titled retained Surgical Instruments and Other Items, indicated "...Guidewires inserted as part of the central line placements have not uncommonly been lost in vessels and require interventional radiographic retrieval. A recommendation for the guidewires is to place a clamp on the end of the guidewire before inserting so it cannot slip away and replace the clamp as soon as possible after the catheter

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has been slipped over the guidewire to prevent the wire from being lost in the vessel as the catheter advanced..."

Review of the [redacted]11 Universal Protocol Pre-Procedural Safety Checklist form did not include the guidewire as one of the items to be accounted for and checked before and after vascular catheter insertion procedure, to ensure that any members of the team disposed the guidewire appropriately after the insertion of the catheter, and not left in the patient's body.

In an interview on 6/24/11 at 5:30 PM, the Director of Risk Management stated that the facility did not have policy and procedure for vascular catheter insertion because the procedure was done by a physician. She further stated that although vascular catheter insertion is an invasive procedure, there was no policy to include the counting of guidewire in the Pre-Procedural Safety Checklist form.

The facility's failure to prevent the retention of a guidewire during catheter insertion is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1.

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