

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050570	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/21/2011
NAME OF PROVIDER OR SUPPLIER Fountain Valley Regional Hospital & Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 17100 Euclid St, Fountain Valley, CA 92708-4004 ORANGE COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00292251 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25720, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>Health & Safety Code Section 1280.1(c):</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 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.</p> <p>The CDPH verified that the facility informed the patient or the party responsible for the patient of the</p>		<p>The plan of correction is prepared in compliance with federal regulations and is intended as Fountain Valley Regional Hospital's (the "hospital") credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.</p> <p><u>Organization Minutes:</u> The confidential and privileged minutes are being retained at the facility for agency review and verification if required.</p> <p><u>Exhibits:</u> All exhibits including revisions to Medical staff Bylaws, reviewed/revised or promulgated policies and procedures, documentation of staff and medical staff training/education are retained at the facility for agency review and verification upon request.</p> <p><u>Plan Of Correction:</u></p> <p>a) The following corrective actions were accomplished to correct the deficient practice both temporarily and permanently.</p> <p><u>Policy & Procedures:</u></p> <p>The Chief Operating Officer and the Director of the Cardiac Catheterization Lab reviewed the following Policies and Procedures:</p> <p>1. Hemostasis, in which the following change was made: the sentence "Remove patient from the Catheterization Lab table with a slide board prior to placement of hemostasis devices" was added.</p> <p>2. Patient Care: Preparation of Patient for Cardiac Catheterization, in which the following language was added to the policy and procedure:</p> <ul style="list-style-type: none"> ▪ The catheterization lab RN will review the 	<p>1/20/2012</p> <p>1/20/2012</p>

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Event ID:LQXV11

10/7/2013

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

[Signature]

CEO

10/18/13

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 15

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.

POC accepted 10/22/13 Surveyor 25720

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	<p>adverse event by the time the report was made.</p> <p>Deficiency Constituting Immediate Jeopardy:</p> <p>T22 DIV5 CH1 ART3-70215(a)(2) Planning and Implementing Patient Care (a) A registered nurse shall directly provide: (2) The planning, supervision, implementation, and evaluation of the nursing care provided to each patient. The implementation of nursing care may be delegated by the registered nurse responsible for the patient to other licensed nursing staff, or may be assigned to unlicensed staff, subject to any limitations of their licensure, certification, level of validated competency, and/or regulation.</p> <p>T22 DIV5 CH1 ART3-70215(b) Planning and Implementing Patient Care (b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission.</p> <p>T22 DIV5 CH1 ART6-70435(a)(1)(A) Cardiovascular Surgery Service Staff (a) Cardiovascular catheterization laboratory. (1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training. He shall be responsible for: (A) Implementing established policies and procedures.</p>		<p>chart and assess the patient to ensure the following are complete and accurate; informed consent, current medication record, including anticoagulants and antiplatelet agents, vital signs, body mass distribution, laboratory reports, and allergies. The RN will notify the physician immediately if abnormalities exist including if anticoagulants or antiplatelet agents were given within 24 hours of the anticipated start time of the procedure. The RN will assess and determine the number of catheterization lab staff required to transfer or turn the patient.</p> <ul style="list-style-type: none"> ▪ The catheterization lab RN will complete the assessment of patient pre- procedure, during procedure and post procedure. The documentation of ongoing assessment will be maintained in the catheterization lab record. ▪ The patient is brought to the catheterization lab via gurney or bed. The patient is transferred to the catheterization lab table using the slide board covered in a standard sheet; the staff will not use the nylon covering used to protect the mattresses in the transfer of a patient. ▪ The slide board is carefully removed, arm boards inserted, and safety strap are applied across the torso of the patient. <p>3. The Femostop policy and procedure was revised to include the following language:</p> <ul style="list-style-type: none"> ▪ Remove patient from the table with the slide board to the gurney or bed prior to placement of the femostop. ▪ Three staff members must be present for the application of the femostop device. Staff member #3 continues to hold manual pressure to ensure hemostasis until the device is applied. Staff member #2 and #3 will assist with the application of the device, each on either side of the gurney or bed 	<p>2013 JAN 21 10:03 AM</p> <p>1/20/2102</p>

Event ID:LQXV11

10/7/2013

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	<p>T22 DIV5 CH1 ART6-70435(a)(1)(B) Cardiovascular Surgery Service Staff (a) Cardiovascular catheterization laboratory. (1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification in cardiology by either the American Board of Internal Medicine or the American Board of Pediatrics or have equivalent experience and training. He shall be responsible for: (B) Supervision and training of all personnel, including in-service training and continuing education.</p> <p>The above regulations were NOT MET as evidenced by:</p> <p>Based on observation, interview, and review of the medical record and hospital documents, the hospital failed to ensure the RN had conducted an assessment of Patient A and advocated for the patient's safety prior to using the Femostop (a pressure device) being applied to the patient while lying on a narrow and slippery procedure table in the cardiac catheterization lab on [REDACTED] 1. In addition, the patient was at high risk for bleeding due to the administration of anti-blood clotting medications prior to and during the procedure. Application of the Femostop device required the patient to be turned side to side to place a belt underneath the hips to keep the pressure device in place on the right groin. While Patient A was turned on to her right side during the application of the pressure device by two technicians who were not validated to be competent to use the pressure device as per the hospital's P&P (policy and</p>		<p>4. The Sheath Removal, Arterial and Venous policy and procedure was revised to state: Remove patient from the Cath Lab table with slide board prior to manual compression or placement of hemostasis assist devices.</p> <p>5. The Chief Operating Officer, Director of the Cardiac Catheterization Lab, and Director of Perioperative Services reviewed the Policy and Procedure entitled Falls Prevention and Resource and determined that no changes would be required. Page 3 of the Policy and Procedure indicates that a patient on Benzodiazepines, Narcotic Analgesics, Sedatives/Hypnotics, or Blood Thinners would be considered "at risk for falls." This alone would place all cardiac catheterization lab or interventional radiology patients at risk. The policy also requires that the patient be assessed upon transfer to another unit.</p> <p><u>Training:</u> The Director of the Cardiac Catheterization Lab or her designee educated the cardiac catheterization lab staff on the changes in the Policies and Procedures as noted above.</p> <p>The Director of Cardiac Catheterization Lab and the Director of Education reviewed the staff competencies for Femostop, and developed new competencies. Any staff member that has not completed the competency for Femostop will not be able to apply Femostop until they have completed the competency. This information has been incorporated into new Cardiac Catheterization Lab staff orientation and the Cardiac Catheterization Lab staff will be re-evaluated on the competencies annually.</p>	<p>1/20/2012</p> <p>1/20/2012</p> <p>1/20/2012</p> <p>1/20/2012</p>

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10/7/2013

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	<p>procedure) Patient A's head, shoulders and chest slipped down off the table. The upper body of the patient fell to the floor. The patient hit her head and sustained a subdural hematoma (a blood clot formed underneath the skull). Patient A's neurological condition deteriorated following the fall and the patient passed away two days later.</p> <p>Findings:</p> <p>An onsite visit to the hospital was conducted on 12/9/11. The procedure room in the cardiac cath lab was observed at 1010 hours, with the Director of the cardiac cath lab, the Director of Quality Services, the Chief Operating Officer, and CRT 1 (Certified Radiologic Technician). Observation of the procedure table showed a long table which narrowed at the head and neck area. A C-Arm x-ray machine was at the head of the table. The control room with a window was located at the end of the room to the foot of the patient. CRT 1 stated she was one of the two staff who had turned Patient A when the patient fell from the table. CRT 1 stated the arm boards placed along the side of a patient to hold their arms and body in place during the procedure had been removed in order to turn Patient A onto her side. CRT 1 stated she and the other technician were unaware that the nylon sheet used to cover the air mattress on the patient's hospital bed had been used to move the patient from the bed onto the procedure table and was directly underneath the patient when the patient was turned to her side. CRT 1 stated the nylon sheet was slippery on both sides. CRT 1 stated when applying the Femostop device, a belt was</p>		<p>The Director of the Cardiac Catheterization Lab reviewed the competencies for all new Cardiac Catheterization Lab Staff and confirmed that required competencies were completed within six months of hire. The Director Cardiac Catheterization Lab reviewed the required competencies for existing employees to assure that staff has all required competencies. Any staff member that has not completed a required competency will not be able to complete that procedure until the competency has been completed.</p> <p>The Risk Manager and the Nurse Educator educated the patient care related staff regarding the incident and the lessons learned from the incident via the document entitled "Patient Safety Alert, Preventing Falls" dated December 2011.</p> <p>The Director of the Cardiac Catheterization Lab and the Director of Perioperative Services re-educated their staff on the Fall Prevention Policy and Procedure and emphasized that all cardiac catheterization lab and interventional radiology patients are at risk for falls and the fall risk reduction strategies that should be employed.</p> <p>The Department Directors educated their regular patient care related staff (defined as part time and full time employees and contract staff) by January 20, 2012. All other patient care related staff were educated by the second shift worked or by January 20, 2012.</p>	1/20/2012	1/20/2012

Event ID:LQXV11

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	<p>needed to be placed under the patient to hold pressure against the patient's groin insertion site to help stop the bleeding. CRT 1 stated the patient was rolled on her left side towards her, the belt was then placed underneath the patient, and the patient was rolled onto her back. CRT 1 stated she then rolled Patient A to the right towards the other Technician, CRT 2. CRT 1 stated she placed her left hand on the patient to hold her in place and reached with her right hand to pull the belt out from underneath the patient. CRT 1 stated the patient's chest and head slipped off the table at a 45 degree angle. CRT 1 stated she ran to the other side of the table but the two technicians were unable to lift the patient back onto the table. CRT 1 stated she supported the patient's head and the patient was eased to the floor.</p> <p>Medical record review for Patient A was initiated on 12/9/11. The patient was admitted to the hospital on [REDACTED] 11, complaining of left foot pain. Review of the physician's History and Physical dated [REDACTED] 11, showed the patient had diagnoses which included diabetes (elevated blood sugar), hypertension (elevated blood pressure) and severe peripheral vascular disease (decreased blood flow to the lower extremities). Examination of the left foot showed an ulcer between the third and fourth toes, likely due to lack of blood supply. The patient was five feet tall and weighed 199.98 pounds.</p> <p>Review of the Vascular Surgery Progress notes for Patient A showed the patient underwent a procedure using a special dye and x-ray to see how blood flowed through the blood vessels and an</p>		<p><u>b)The following individuals were responsible for assuring the corrective actions were completed.</u></p> <p>The Chief Operating Officer and Director of the Cardiac Catheterization Lab. The Chief Nursing Officer The Director of the Perioperative Services</p> <p><u>c) Fountain Valley Regional Hospital and Medical Center completed the following monitoring processes to prevent the recurrence of this type of event in the future.</u></p> <p>The Director of the Cardiac Catheterization Lab or their designee reviewed thirty (30) reports per month for four months from the XPer system to verify that the patient was transferred using a slide board or standard sheet, and the timeliness of the transfer of the patient to the gurney or bed following the procedure. 90% compliance was expected. Any months falling below 90% compliance resulted in an additional month of auditing. Any noted non-compliance resulted in re-education and disciplinary action as appropriate.</p> <p>The Director of the Cardiac Catheterization Lab or their designee reviewed thirty (30) medical records per month for four months to verify that the Femoston was applied after the patient was transferred to either a gurney or bed. For months where there were less than thirty (30) cases where Femoston is applied 100% of cases were reviewed.</p>	<p>1/20/2012</p> <p>1/20/2012</p>

Event ID:LQXV11

10/7/2013

1:37:18PM

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	<p>arterectomy (a procedure that utilizes a catheter with a sharp blade on the end to remove plaque from a blood vessel) of the superficial femoral artery (a large artery in the thigh) on [REDACTED] 11, in the cardiac cath lab. The physician documented the patient was to return on [REDACTED] 11, for intervention on the tibial (lower leg) arteries. The patient would be started on Plavix (anticoagulant).</p> <p>Review of the Medication Administration Record for Patient A showed Plavix and Lovenox (anticoagulant) were administered on [REDACTED] and [REDACTED] 11, and also on [REDACTED] 11 at 0900 hours, just previous to the second cath lab procedure.</p> <p>Review of the Procedure Log dated [REDACTED] 11, showed Patient A returned to the cardiac cath lab at 0930 hours, for a percutaneous transluminal angioplasty (a procedure used to dilate an area of arterial blockage with the help of a catheter which is introduced through the skin of the groin and placed within a blood vessel to cut or shave away deposits of fat and other substances that accumulate in the lining of the artery wall). Documentation in the Procedure Log at 0931 hours, showed "no" was documented to the question if the patient had received the anticoagulant medication, Lovenox. The patient was given sedation using narcotics. Documentation showed the catheter insertion site was the right groin. Heparin 9,000 units (an intravenous fast acting anti-coagulant medication) were administered at 1025 hours, during the procedure. Documentation showed the procedure was completed at 1132 hours, without complications. The first closure device to the right</p>		<p>90% compliance was expected. Any months falling below 90% compliance resulted in an additional month of auditing. Any noted non-compliance resulted in re-education and disciplinary action as appropriate.</p> <p>The Chief Operating Officer and Director of Nursing or their designees monitored through direct observation thirty (30) transfers from the bed or gurney to a procedural table each month for four months. The monitoring focused on the type of device used for transfer and the adequacy of the number of staff used during the transfer. 90% compliance was expected. Any months falling below 90% compliance resulted in an additional month of auditing. Any noted non-compliance resulted in re-education and disciplinary action as appropriate.</p> <p>The Director of the Cardiac Catheterization Lab or her designee audited thirty (30) catheterization lab records per month for four months to assure that the documentation supported that the RN assessed for current medications including anticoagulants and antiplatelet agents, body mass distribution, the number of staff required for transfer or turning of the patient.</p> <p>The Director of Education or her designee audited the new hire and annual competencies to assure that they were reviewed and that they are complete.</p> <p>The results of monitoring were reported to the Performance Improvement Committee, the Medical Executive Committee and the Governing board for review and action as required.</p> <p><u>Disciplinary Action:</u> Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.</p>	<p>1/20/2012</p> <p>1/20/2012</p> <p>1/20/2012</p> <p>1/20/2012</p>	
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	<p>groin was inserted, but failed. A second closure device was inserted at 1140 hours. At 1143 hours, documentation showed the insertion site was "bleeding, pressure held." At this time the patient was fully awake and able to move extremities on command. The patient was administered a medication to lower her blood pressure at 1200 hours. Documentation at 1213 hours, showed the "patient appears to have fallen off procedure table."</p> <p>A CT scan (computed tomography, a special x-ray machine which takes pictures of the brain, skull and sinuses as well as blood vessels in the head) of Patient A's head/brain was done on [REDACTED]11 at 1244 hours. Review of the report showed a 3 mm (millimeters) size subdural hematoma and a large right scalp hematoma (mass of clotted blood).</p> <p>Review of the Neurosurgeon consultation dated [REDACTED]11 at 1746 hours, showed Patient A's neurological function was at baseline on exam. The physician documented the size and type of subdural hematoma seen on the CT scan usually did not cause any danger and did not require intervention at this point. A repeat CT scan was recommended in the morning.</p> <p>Documentation in the Physician's Progress Notes dated [REDACTED]11 at 0000 hours, showed Patient A was neurologically worse with questionable seizure activity.</p> <p>Review of the findings of a MRI (magnetic resonance imaging, a medical imaging technique is used to visualize detailed internal structures) of the brain done on [REDACTED]11 at 0046 hours, showed a</p>			2013 OCT 21 PM 3 24

Event ID:LQXV11

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1:37:18PM

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	<p>significant increase in the size of the subdural hematoma to 18 mm in thickness, now bilateral, right greater than left. In addition there was a new subarachnoid hemorrhage (bleeding) measuring up to 7 mm on the right and 3 mm on the left (bleeding in the area between the brain and the thin tissue that covered the brain).</p> <p>Review of the findings of a CT scan of the brain done [REDACTED]11 at 1537 hours, showed the size of the subdural hematoma and the hemorrhage to be without change; however, an evolving right MCA infarct (a stroke in the brain tissue that is supplied blood by the middle cerebral artery) was noted.</p> <p>Documentation in the Physician's Progress Notes dated [REDACTED]11 at 1630 hours, showed Patient A was nonresponsive to verbal stimuli.</p> <p>Review of the findings of a MRI of the brain done [REDACTED]11 at 1835 hours, showed a new large right MCA territory acute infarct with extensive edema with mass effect (a growing mass).</p> <p>Documentation in the Physician's Progress Notes dated [REDACTED]11 at 0830 hours, showed no improvement in Patient A's neurological condition. Documentation showed at 1000 hours, the patient's family had decided to proceed with comfort measures only. The patient passed away the same day.</p> <p>Review of the Certificate of Death dated [REDACTED]11, showed the immediate cause of death was cardiopulmonary arrest due to subdural hematoma</p>			2011 OCT 21 PM 3 25

Event ID:LQXV11

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1:37:18PM

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	<p>and mechanical fall.</p> <p>CVT 1 (Cardiovascular Technician) was interviewed on 12/21/11 at 0905 hours. CVT 1 stated he assisted the physician during Patient A's procedure on [REDACTED] 11. CVT 1 stated he had just applied the second closure device and was holding pressure on the patient's groin when he was relieved for lunch by CRT 2 at about 1130 hours. CVT 1 stated pressure would be held on the patient's groin for approximately 20 minutes at that point in the procedure. CVT 1 stated the RN in the room was in charge and would decide if more pressure was needed and if the physician was to be notified for excessive bleeding.</p> <p>RN 1 was interviewed on 12/21/11 at 0935 hours. RN 1 stated he was the RN in the cardiac cath lab room during Patient A's procedure on [REDACTED] 11. RN 1 stated he helped move the patient from the bed onto the table prior to the procedure. RN 1 stated they usually used the sheet on the bed to move the patient onto the table; however, in this case the only bed covering was the thick nylon "slippery" sheet. RN 1 stated he was relieved by RN 2 for lunch at about 1130 hours, at the end of the procedure. When asked, RN 1 stated the RN was in charge of the technicians in the room.</p> <p>CRT 2 was interviewed on 12/21/11 at 0955 hours. CRT 2 stated she came into the cath lab on [REDACTED] 11, as Patient A's procedure was ending and relieved CVT 1 for a lunch break. She continued holding pressure to the patient's groin. CRT 2 stated, by about noon RN 2 and CRT 1 were the</p>			2013 DEC 21 PM 3 25

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050570	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/21/2011
NAME OF PROVIDER OR SUPPLIER Fountain Valley Regional Hospital & Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 17100 Euclid St, Fountain Valley, CA 92708-4004 ORANGE COUNTY		
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	<p>only staff in the room with her and the patient. CRT 2 stated the physician and RN 2 were in the control room. RN 2 came into the procedure room as needed, but was monitoring the patient's vital signs in the control room. When asked, CRT 2 stated there was a window between the control room and the procedure room; however, CRT 2 stated they could not visualize the patient well from there.</p> <p>CRT 2 stated as she was holding pressure on Patient A's groin she observed more than the usual amount of bleeding. CRT 2 stated she was trying to decide why the patient was still bleeding and asked RN 2 if the second device to stop the bleeding had failed. CRT 2 asked the RN 2 if device failure had been charted by RN 1 or CVT 1 prior to their leaving on their meal breaks. CRT 2 stated RN 2 told her she did not know, so CRT 2 continued to hold pressure. CRT 2 stated the physician called out from the control room to ask how the patient was doing and CRT 2 told him the patient was still bleeding. CRT 2 stated RN 2 was in and out of the control room and at one point administered medication to lower the patient's blood pressure. After about 25 minutes of holding pressure the physician gave the order to apply the Femostop pressure device. CRT 2 stated the Femostop was not used a lot, maybe one to two times a week. CRT 2 stated the pressure device was applied while the patient remained on the procedure table, often with only two staff.</p> <p>CRT 2 stated Patient A carried the bulk of her weight from her head to her groin. CRT 2 stated she did not think the patient was able to ambulate as</p>			2013 OCT 21 PM 3:25

Event ID:LQXV11

10/7/2013

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	<p>the muscles in her legs appeared atrophied (muscles shrunken). CRT 2 stated while she and CRT 1 were applying the pressure device they were the only staff in the room, as RN 2 and the physician were in the control room. When asked, CRT 2 stated she did not see RN 2 physically assess the patient prior to the pressure device being applied.</p> <p>CRT 2 stated, to apply the pressure device they had to place a belt underneath the patient at the level of the hip bone. CRT 2 stated she was positioned on the patient's side two to three inches below the waist of the patient. She held pressure to Patient A's groin with her left hand, rolled the patient towards CRT 1 and pushed the belt under the patient. The patient was then rolled back towards her for CRT 1 to reach underneath the patient to pull out the belt. When the patient slipped off the table, CRT 2 stated she had one hand holding pressure on the groin and one hand on the patient's hip. CRT 2 stated they had to lower the patient to the ground as they could not lift her back to the table. CRT 2 stated the patient was alert at that time but complaining of pain on the right side of her head.</p> <p>CRT 1 was re-interviewed on 12/21/11 at 1055 hours. CRT 1 stated when she entered the cath lab room on 11, CRT 2 was holding pressure on Patient A's groin. After ten to fifteen minutes CRT 2 showed her the patient was continuing to bleed from the insertion site. CRT 1 stated CRT 2 had informed the physician of the bleeding and he ordered the Femostop be used. When asked, CRT</p>			2013 OCT 21 PM 3 25	

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	<p>1 stated RN 2 did not assess the bleeding at the groin insertion site. CRT 1 stated the physician had ordered the pressure device based on CRT 1 and CRT 2's observation of the bleeding. CRT 1 stated RN 2 was in the control room monitoring the patient's vital signs and finishing her charting.</p> <p>CRT 1 stated she was positioned at the patient's hip. The patient was awake, very passive, and it did not appear she tried to move herself. The patient's arms were crossed over her chest. CRT 1 stated she removed the arm board from the table. CRT 1 stated when the patient slipped from the table it happened very fast.</p> <p>When asked how she learned to apply the Femostop device, CRT 1 stated she was taught to use it during her orientation to the cath lab. When asked, CRT 1 stated the pressure device was usually applied while the patient was still on the procedure table and usually two staff helped to apply it unless more staff was available.</p> <p>RN 2 was interviewed on 12/21/11 at 1120 hours. RN 2 stated she entered the cath lab room to relieve RN 1 for a meal break, at about 1130 hours on 12/21/11. RN 2 stated the first closure device used for Patient A had failed. A second device had been inserted by the physician with manual pressure applied by the CRT. RN 2 stated she thought the second device had been successful, she did not know it had not worked prior to CVT 1 leaving for a break, relieved by CRT 2. RN 2 stated she had looked at factors which would have caused the patient to bleed. RN 2 stated the patient's blood</p>			2013 OCT 21 PM 3 25

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	<p>pressure was elevated so she administered medication to decrease it, hoping that would also help the bleeding. When told by CRT 2 the bleeding had continued, RN 2 stated she had asked the physician for an order for the Femostop device. When asked how the device was applied, RN 2 stated at least two staff were needed to apply the pressure device, and it depended on how much the patient was bleeding. RN 2 stated typically if there was a three man crew, two staff would apply the pressure device.</p> <p>When asked about the RN's responsibilities in the cath lab room, RN 2 stated directing patient care was her primary responsibility. RN 2 stated she supervised the technicians in the room. RN 2 stated it was a team decision on how many staff was needed to apply the Femostop device. When asked if she had assessed the size of the patient in relation to the width of the table, RN 2 stated she had seen the patient a few days before, during the first procedure on [REDACTED] 11; however, the patient was "overly large which did not stand out in her mind." RN 2 stated the patient had been draped when she entered the room on [REDACTED] 11, to relieve RN 1.</p> <p>The Director of the Cardiovascular Lab was interviewed on 12/21/11 at 1320 hours. The Director stated she thought staff was instructed in the use of the Femostop during their orientation, but was not sure if this was documented. The Director stated she had been taught to move the patient from the procedure table to the gurney before applying the Femostop, and she was not aware the device was applied to the patient while on the</p>			2013 OCT 21 PM 3 25

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	<p>procedure table at this hospital. When asked, the Director stated the device was usually applied by two staff, but that this was a team decision. When asked if the RN should assess a patient's groin for continued bleeding, the Director stated not necessarily, as the technicians had competencies to do this. The Director stated the RN was in charge of the room if the technicians had questions. When asked if the RN was in charge of the patient's safety, the Director stated, yes.</p> <p>The Job Description for RNs working in the cath lab was reviewed with the Director of the Cardiovascular Lab on 12/21/11 at 1420 hours. Documentation showed the RN was to evaluate, revise and update patient care during the catheterization period, setting priorities and delegating duties as indicated. The RN was to maintain a patient care environment that was clean, orderly and supported safe patient care. Review of the job description for the Special Procedures technicians did not show they were to assess a patient for bleeding. The Director verified assessment was not listed as a job responsibility for the cath lab technicians.</p> <p>The P&P for the use the Femostop in the cardiac cath lab, last revised 6/09, was reviewed with the Director of the Cardiovascular Lab on 12/21/11 at 1445 hours. The scope of the policy encompassed physicians, nurses and technicians who have been shown how to apply the Femostop device by a clinical nurse educator, consultant or manager are deemed competent in its application. The competency forms for the use of the Femostop device for CRT 1 and CRT 2 were reviewed with the</p>			2013-01-21 PM 3:25

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	<p>Director. For CRT 1, the item was not dated or initialed to show the technician's competency for the use of the Femostop had been validated. For CRT 2, a date of 2/09 was documented for validation of the use of the Femostop device; however, the item was not initialed by the validator. Further review of the competency form showed the validator for the form was another CRT. When asked, the Director verified the P&P did not show another CRT was allowed to validate the competency a staff member for the use of a Femostop device.</p> <p>The facility failed to ensure the RN in the catheterization laboratory assessed, planned and supervised the care provided to Patient A and advocated for her safety, and to ensure the competency validation P&P was implemented and the staff was trained to assist Patient A prior to a pressure device being applied to the patient while lying on a narrow and slippery procedure table in the cardiac catheterization laboratory.</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 1280.1(c).</p>			2013 OCT 21 PM 3 25	

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