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
	050107	A. BUILDING _____ B. WING _____	08/29/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Marian Regional Medical Center	1400 E Church St, Santa Maria, CA 93454-5906 SANTA BARBARA COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00501103 - Substantiated Representing the Department of Public Health: Surveyor ID # 2568, 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 & Safety Code Sections 1279.1 (a) and (b)(1)(D): (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events,			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: President & CEO (X6) DATE: 9/12/17

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s). 1 thru 8*

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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	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. 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. A guidewire from a heart catherization procedure was left inside Patient A's heart vicinity and discovered four years later during a doctor's visit for complaints of chest discomfort. Title 22, California Code of Regulations, Section 70223(b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Based on record review and interview the facility failed to implement its policy and procedure on retained surgical items relating to surgical count for miscellaneous items to ensure a guidewire (needle thin like wire used to direct the catheter placement)		Accepted 9/12/17 PQ Chilcutt CA DEPT OF PUBLIC HEALTH 2017 SEP 12 PM 1:38 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE *Accountability:* Chief Nurse Executive Officer *Immediate Action:* 1. 100% of the involved Provider cases were reviewed (over 400 cases going back multiple years). Each record was reviewed (operative reports, radiology reports, post-operative images, and other documentation) to assure additional patients did not have evidence of a retained guidewire. No evidence of a retained guide wire and no patient admissions suggesting complications of retained guidewire.	Completed by 10/30/16

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	was removed/pulled out after use in one patient (Patient A). As a result of these failures, the facility retained a 45 centimeter guidewire in the patient's superior vena cava (SVC -large vessel on the top of the heart) resulting in chest pain and further surgical procedures to remove the retained foreign object. According to the Association of Peri-Operative Registered Nurses (AORN) Journal, dated 7/15/10, recommended practices for prevention of retained surgical items are intended guidelines adaptable to various practice settings including traditional operating rooms, ambulatory surgery centers, physician offices, cardiac catheterization laboratories, endoscopy suites, radiology department, and other areas where surgery and other invasive procedures may be performed. (Mitchell, Sheila. "Recommended Practices for Prevention of Retained Surgical Items." Perioperative Standards and Recommended Practices (1982): 305-22). According to the Joint Commission Publication, dated 10/15/13, "Unintended Retained Foreign Objects (URFB)" refers to any foreign object related to operative or invasive procedure that is left inside a patient. Objects most commonly left behind after a procedure include small miscellaneous items, including un-retrieved device components of broken parts instruments, stapler components, parts of laparoscopic trocars, catheters and guide-wires. The most common root causes of URFB are absence of policies and procedures and failure to comply with existing policies and procedures." [Bagian, James. "Preventing unintended retained foreign objects."		2. A process was immediately implemented in Anesthesia requiring two individuals (the physician and another individual participating in the procedure) to verify through observation, the removal of the guidewire following line placement. 3. A formal case review discussion was conducted with the Anesthesia Group informing them about the event and the expectation of verification and validation of guidewire removal after line insertion. 4. A formal case review discussion was conducted with the Radiology Group to review the radiology report. The Radiologists agreed to expand the description of the markings and specifications of lines identified in radiology reports.	Completed by 9/30/16 Completed by 9/30/16 Completed by 9/30/16

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	The joint commission Sentinel Event Alert (17 Oct. 2013). During an interview on 9/2/16 at 10:45 a.m., the facility's Director of Patient Safety (DPS) stated, "I was informed by the attending physician (AP 1), of the retained guidewire. AP1 was notified by an outside medical provider (OMP - not connected with the facility) currently taking care of the patient. I went to the Radiology Department to look at the x-ray films done four years ago after Patient A's surgery and sure enough the guidewire was there but if one was not looking for it, there was no way of knowing it was there. This is a device or item that operating room (OR) personnel do not count or account for. I have no answer to how the guidewire got retained after the CVC procedure. I spoke to the patient and was told it will be removed by the OMP." A review of the clinical record for Patient A on 9/2/16, revealed on 1/18/12, the patient underwent a central venous (CV) and pulmonary artery catheterization (PAC - catheter to the side and under the heart to monitor heart activity and lung pressure) in the facility's operating room 1(OR 1).The procedure was performed by AP 2 in preparation for an open heart surgery which was scheduled on the same day to be done by AP 1. Following the procedure and surgery the patient stayed at the facility for five days and was discharged to home on1/23/12. The procedure notes dated 1/18/16 indicated two different kinds of catheters were inserted through the patient's right and left internal jugular vein (IJV -large		***Systemic Action:*** 1. A central line insertion checklist was designed to include "removal of the guidewire" in the electronic health record to be completed by practitioners documenting insertion of central lines. ***Monitoring:*** 1. 100% of cases performed by the involved practitioner have been evaluated for compliance to expectations and outcomes. There have been no additional events since the occurrence in 2012. 2. Based on monitoring and reporting processes implemented throughout the hospital, no further events have been identified since the discovery of this retained guidewire event. 3. The analysis and action plan for significant events is reported to the Quality Committee, Medical Executive Committee and Governing Board.	Completed by 10/30/16 Completed by 10/30/16 and ongoing

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	veins at the side of the neck). The right catheter measured 16 centimeters (cm) and the left was 110 cm long. Record review on 9/6/16 of the facility's additional documentation entitled "Summary of incident" dated 9/2/16 indicated, on 8/25/16 the facility was notified by an outside medical provider (Cardiovascular Surgeon) of an incidental discovery of a retained foreign body (FB), a guidewire in Patient A's superior vena cava (a large vein on the right side of the heart). According to the "Summary of incident" dated 9/2/16, the risk manager indicated in the report, "The facility presumed the guidewire was from an open heart surgery performed at (here at the facility) in 2012." The facility's risk manager reviewed Patient A's case on 9/2/16, as well as the imaging reports from January 17, 18, and 19 of 2012 and confirmed the presence of the guidewire on the images taken post operatively at the facility in 2012. On 9/2/16 at 10:50 a.m., the DPS presented a sample of the same CV and PAC kit used on the catheterization procedure of Patient A on 1/18/12, four years ago. The guidewire measured 45 cm. in length. The risk manager confirmed this was the same type of CV PAC kit used on patient A. During an interview on 9/7/16 at 2:50 p.m., AP 2 stated, "I have placed a thousand of these catheters in my career and I cannot offer any explanation as to how the guidewire got retained. The guidewire sticks out as the catheter is inserted thru it. As soon as the catheter is placed, the guidewire is removed. If it accidentally slipped in, the radiologist could have picked it up during X-ray. This is an item not			

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	included in the OR count." According to AP 2 the radiologist should have identified the wire if it was there as they rely on him for clearance. AP 2 also indicated if he had known the guidewire was there it should have been removed as soon as the patient was stabilized post op. During interviews on 9/7/16 at 3:20 p.m., 9/8/16 at 9:50 a.m., and 9/8/16 at 10 a.m., OR staff 1 (ORS 1) stated, "I did not assist AP 2 with the CV and PAC procedure and we do not account for the guidewires in the OR." The ORS 2 stated, "I was with AP 2 during the procedure but my role was just to hand over the items as requested. The physician pulls out the guidewire as soon as the catheter is in place. We do not count guidewires in the OR." ORS 3 also stated, "We do not count guidewires in the OR." Review of the facility's policy and procedure (presented by the risk manager and according to the risk manager, the same policy the facility has used "since day one" entitled, "Prevention of Retained Surgical Items Policy", undated, set forth the following: "III A. Surgical items - supplies, devices, equipment used in and around a surgical incision or wound, to aid in the performance of an operation or procedure, to provide exposure and to absorb blood and body fluids." Subpart 4. "Small miscellaneous items are other objects used during surgical procedures that are single use....but not limited to...disposable			

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	instrument inserts... vascular inserts. Section C. of the policy entitled "Surgical Count" indicated "A process involving two people whereby they look at items together, one person manually count's, separates each item and audibly counts the number of items. Surgical counts must be performed in procedures in which an incision is made or a wound is created and surgical items are used. The surgical count is performed to identify any packaging errors and to monitor the number of items used during the operation or procedure." A review of Patient 1's cardiologist's discharge summary notes dated 9/2/16 indicated, Patient A was seen by the cardiologist due to complaint of chest pain. According to the notes, a chest x ray at the physician's clinic identified a retained FB. The cardiologist presumed the FB was a guidewire from a neck line insertion placed at the time of the patient's coronary artery bypass graft (CABG) in the right IJV. The notes further indicated an unsuccessful attempt to remove the FB. Patient A was referred to another outside medical provider for the FB removal. The failure of the OR staff to follow the facility's policy and procedure pertaining to small miscellaneous item counts resulted in the retention of a 45 cm. guidewire inside the patient's superior vena cava causing chest pains and additional surgical procedures to remove the retained foreign object The facility's failure to implement surgical care and services in compliance with section 70223 (b) (2) for Patient A with a retained foreign object is			

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	a deficient practice that has caused, or is likely to cause, serious injury or death to the patient. 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).			