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
	050082	A. BUILDING _____ B. WING _____	02/21/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST JOHNS REGIONAL MEDICAL CENTER	1600 N Rose Ave, Oxnard, CA 93030-3722 VENTURA COUNTY

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s). 1 thru 11*

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	Health and Safety Code Section 1279.1 (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. 1279.1 (b) (2) (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. Title 22 California Code of Regulations, Section 70433 (a) Administration; Written policies and procedure shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals in administration. Polices shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. These polices and procedure shall			

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	include provision for at least: (4) Recommendations regarding equipment used, procedures performed and staffing patterns in the catheterization laboratory and cardiovascular surgery units. Title 22 California Code of Regulations, Section 70435 (b) Cardiovascular operative service. (1) A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification by the American Board of Thoracic Surgery or the American Board of Surgery with training and experience in cardiovascular surgery. He shall be responsible for: (A) Implementing established policies and procedures. (C) Training and supervising the clinical perfusionists. Based on record review, interview and observation the hospital failed to develop and maintain written policies and procedures to ensure that the by- pass equipment used during open heart surgery was safe, and that emergency procedures were developed in case of equipment malfunction. The physician responsible for the service failed to implement policies and procedures for perfusion services and failed to ensure clinical perfusionists operated by-pass equipment according to manufacturer's instructions and maintained the function of a heart-lung machine. These failures resulted in the malfunction of a heart-lung machine			

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	during surgery that led to the death of Patient 1. (A heart-lung machine functions as the heart and lungs of a patient when blood is diverted from the patient and before it can enter the heart, the blood is run through a machine where it is oxygenated and then sent back into the patient. A perfusionist sets up and operates the heart-lung machine during surgery). Findings On 11/9/15 the facility reported to the Department that Patient 1 expired in the operating room during heart surgery on 11/4/15. Review on 5/11/16 at 5:00 p.m. of Patient 1's autopsy report signed by the forensic pathologist on 5/10/16 revealed that during a heart valve replacement and bypass graft procedure Patient 1 died due to the heart-lung machine failure. Review of the physician's discharge summary dated 11/6/15 on 11/12/15 at 1:30 p.m. revealed that Patient 1 was admitted to the facility with respiratory failure secondary to heart dysfunction on 10/30/15. Patient 1 was then stabilized so that a surgical repair of her heart artery and valve could be done 11/4/15. Review of the 11/4/15 operative report on 11/12/15 at 1:30 p.m. revealed that during open heart surgery, Patient 1 was placed on a heart-lung machine. During the surgery, the operative report further revealed that the surgeon determined the tubing from the patient to the machine had to be changed, for anatomical reasons. The surgeon confirmed in interview on 11/12/15 at			

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	2:50 p.m. that Perfusionist 1 (P1) did not have the correct tubing connector available for use with the change of tubing the physician ordered. Operating room staff left the OR and located the correct connector in the supply room. When the change of tubing was accomplished, the surgeon ordered the blood flow to be turned back on. However, the operative reported indicated that no blood flow came back to the patient and the blood in the tubing was black in color (indicating no oxygen was being received in the blood). The operative report further set forth that P1 attempted to resume blood flow to the patient by changing the pump head of the machine while the surgeon and staff provided advanced cardiac life support (ACLS) to the patient for 20 minutes. The surgeon documented and confirmed in interview on 11/12/15 at 2:50 p.m. that after 20 minutes without blood perfusion to the brain or body there was no chance of recovery, ACLS was stopped and the patient expired at 10:10 a.m. The surgeon indicated that since the patient's blood was in the machine rather than the patient there was no hope that ACLS could help the patient. The surgeon also indicated the machine had functioned properly when last used. Interview with Operating Room Staff 1 (the registered nurse responsible for patient care) and operating room staff 2 (operating room tech who assists the nurse and physician) on 11/12/15 at 2:45 p.m. revealed that P1 did not show up on time on 11/4/15 to prepare for the patient's procedure.			

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	During the interview Operating Room Staff 1 said he called the company that employed P1 to ask where he was. Operating Room Staff 1 and Operating Room Staff 2 indicated that P1 arrived an hour late on 11/4/15, and they observed him to hurriedly struggle to get the pump ready, set up the machine and equipment. Operating Room Staff 1 and 2 both confirmed that when the surgeon asked for the blood tubing to be changed, P1 did not have the connectors immediately available at the machine, and another staff had to leave the room to obtain the correct parts. After the surgeon reconnected the tubing, the blood would not flow and Operating Room Staff 1 and 2 said the blood was black purple in color. Operating Room Staff 1 mentioned that when the machine failed he was surprised that P1 did not use the hand crank (a manual mode of operating the equipment) to get the blood back into the patient. Interview with P2 on 1/13/16 at 2:00 p.m., and P3 (both P2 and P3 are perfusionists with the same company that employs P1) on 4/5/16 at 1:00 p.m., revealed that if there was no flow from the pump to a patient, they both stated they would have used the hand crank first to manually get the blood back into the patient rather than changing the pump head. Interview with Operating Room Staff 3 (a registered nurse on orientation) on 11/12/15 at 2:10 p.m. revealed that when P1 said he did not have the part he needed to get the heart-lung machine running she brought a different bypass machine into the operating room for him to use. Operating Room Staff			

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	3 thought the needed part may have been in that machine, but that machine was not used. Interview with P1 (the perfusionist in the operating room on 11/4/15) on 11/17/15 at 1:15 p.m. revealed that when the blood would not flow back to the patient he suspected a pump head malfunction and decided to change it out. After he changed it out and that did not solve the problem, he stated that he attempted to use a hand crank but couldn't connect it. P1 then contradicted himself during the interview and stated there was no time to use a hand crank during the "90 seconds" of no blood flow. He said that he felt ACLS lasted 90 seconds (not 20 minutes as per the surgeon and the operating room staff). P1 revealed that after the surgeon pronounced the patient dead, the machine worked. In interviews with the Surgeon on 11/12/15 at 2:50 p.m. and Operating Room Staff 1 on 11/12/15 at 2:45 p.m., the Surgeon and Operating Room Staff 1 separately confirmed that after Patient 1 had expired, P1 then announced he had the machine working. Interview with P3 on 11/13/15 at 4:01 p.m. revealed that he was called in to assist P1, but entered the operating room after Patient 1 had expired. P3 said he checked the machine and found it was functional. On 4/5/16 after 1:00 p.m. Perfusionist 3 explained that six pages of documentation should be completed for Patient 1's surgery; and provided the pages for review. Review of P1's documentation for Patient 1's surgery revealed that there were three pages. The "Pre-Bypass Checklist" was signed by			

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	P1, but not dated. The Cardiovascular Perfusion Physiologic Flow Sheet (two page document) was signed by P1, but was incomplete and did not contain the following measurements: arterial pressure, venous pressure, pump flow, central venous pressure, and temperature. In addition on page 2 of the Flow sheet there was no documentation of cannulations, when the pump was turned off, tubing changes, attempts to fix the machine, or patient death. P1 charted he was in at 6:30 a.m., but review of the operating room report revealed that P1 arrived in the operating room at 7:15 a.m. Review on 1/13/16 at 3:00 p.m. of the written agreement between the hospital and the company that provides perfusion services (Company PS), signed 2/12/15, revealed the following conditions to be performed by Company PS and its representative agents: the assigned perfusionist for a procedure was to prepare and maintain all necessary equipment for the procedure, set up the heart-lung machine, regulate blood flow, and provide a complete and accurate medical record. Also, as another condition, Company PS was to provide quarterly quality monitoring reports to the hospital. Interview with Quality Staff 1 on 12/21/15 at 1:13 p.m. revealed that an inspection of the failed machine was done by an outside company hired by the facility, but the quality department would not have access to the report. Quality Staff 1 indicated that she had access to recommendations made to protect patient safety and that they were: (1) P1 would no longer operate a heart lung machine at the			

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	facility; (2) the failed machine would not be used, only parts manufactured by the maker of the machine would be used (software, tubing, connectors, hand cranks); and that (3) all perfusionists would be trained on the use of hand cranks and the above changes. Further interview revealed that the facility had no policies or procedures governing the perfusion services or the by-pass machine. Interview with Quality Staff 1 on 2/2/16 at 11:30 a.m. revealed that she was not certain if all recommendations from the company that inspected the failed machine would be followed, and there were no policies or procedures on what parts should be used or stocked. Interview with Quality Staff Manager and the Operating Room Manager on 4/5/16 at 3:20 p.m. revealed that quarterly reports were not provided according to the contract with Company PS, but that the Operating Room Manager prepared a yearly quality report. Further interview revealed there was no documentation that the medical executive committee reviewed Company PS contracted services, as required by facility policy as stated by the quality manager. There was no documentation that the Company PS contract was renewed by the facility board when reviewed on 8/19/15; and there was no end date on the contract. There was no documentation provided that all recommendations made to prevent recurrence in the malfunction of the machine, or to prevent user error were discussed with the Company			

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	PS staff. On 5/17/16 and on 1/20/16 an in-service attendance form containing two perfusionist signatures was provided, however, there was no lesson plan provided with the sign in sheet. The Operating Room Manager and Quality Staff confirmed during interview that there were no facility policies and procedures developed to direct the delivery of perfusion services. Interview with medical office staff and review of P1's personnel file on 3/28/16, at 12:00 p.m. revealed that he currently had all the privileges granted by the facility, including operating a heart-lung machine. There was no documentation of the restriction of his practice. On 4/5/16, at 1:00 p.m., P3 demonstrated how a heart-lung machine operated and showed how the pump head would be replaced. This was not the failed machine used during Patient 1's surgery, but was the same brand and type. P3 indicated that if there was no blood flow back to the patient he would have used the hand crank first to get the blood back into a patient. Review of the manufacturer's instructions for the machine with P3 revealed that the manufacturer's brand of pump head should be used "exclusively" with the machine. P3 indicated that the pump head P1 used during Patient 1's surgery was not the brand recommended, but was an off-brand used by their company. P3 then indicated that since Patient 1's death, only the brand recommended by the manufacturer was used in the facility.			

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	The operating room storage area was toured with Quality Staff 2 on 4/5/16, and revealed the following: nine of the off-brand pump heads were stored and available for use; there was no documentation to support the changes made in the use of pump heads as referred to by P3. Interview with quality staff and the medical director on 5/17/16 revealed that they did not know the exact cause of the heart lung machine malfunction. Review of the autopsy report on 5/11/16 at 5:00 p.m. revealed that Patient 1 died of exsanguination (being without blood) due to the malfunction of the heart lung machine. The facility failed to develop and maintain policies and procedures to ensure that the by-pass equipment used during open heart surgery was safe, that emergency procedures were developed in case of equipment malfunction, that clinical perfusionists operated by-pass equipment according to manufacturer's instructions and maintained the function of a heart-lung machine. 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).			

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Event ID:WYM111 2/22/2018 7:12:03AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Gloria Dammazl TITLE CNEO (X6) DATE March 14, 2018

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Dignity Health.
St. John's Hospitals

Facility ID: 050000035

Penalty Number: 050012274

California Department of Public Health Request for Plan of Correction for State Deficiencies
Letter dated 2/22/18 and received at Dignity Health St. John's Regional Medical Center on 2/16/18.

Plan of Correction for State Deficiencies

Title 22 California Code of Regulations, Section 70433 (a) Administration: Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals in administration.

Policies and Procedures

***Leadership Accountability*:** Medical Director, Cardiothoracic Surgery

Immediate and Systemic Corrective Actions:

1. Perfusion Services policies and procedures regarding equipment used, procedures performed and staffing patterns in the Catheterization Laboratory and cardiovascular surgery units were approved and fully implemented. These are reviewed and updated submitted to the Medical Executive Committee annually. (11/10/17)
2. All perfusion staff were reminded of the importance of following these policies and procedures immediately following this event. An in-service was again conducted on these dates: 7/19/16 and 10/7/16.
3. A formal letter was sent from the President of Dignity Health St. John's Regional Medical Center to the Administrative leader of Vectra (Perfusion Contract) reaffirming discussions about expectations for all perfusionists. (10/5/16)
4. A "Perfusionist Evaluation of On-Pump Cardiac Surgical Cases" checklist was implemented. This checklist included the following parameters and was conducted collaboratively with the perfusionist and the RN Circulator who was assigned accountability for assuring that all parameters were met: (7/18/16)
    - Perfusionist arrived on time according to contract requirements (within 30 minutes).
    - Perfusionist participated in the procedural time out prior to the start of the case.
    - Standard safety checklist completed by perfusionist prior to procedure start.
    - Required documentation for the case is completed and is timely (by the time case is completed).
    - Only Sorin pump heads are used with Sorin bypass machine per manufacturer's guidelines.
    - Any critical events related to the Sorin pump during the procedure are documented and reported through the event reporting system.

Monitoring Plan:

1. The "Perfusionist Evaluation of On-Pump Cardiac Surgical Cases" was monitored with checklists completed by the RN Circulator with all cardiovascular cases involving perfusionists for 12 months following this event. The information gathered was reported to the Hospital Quality Committee, Medical Executive Committee and the Quality Committee of the Community Board per their

minutes. Since there were no opportunities for improvement noted and 100% compliance to these metrics, the ongoing monitoring was discontinued and compliance is reported and monitored through the organization's event reporting process. (12/1/2015)

2. Compliance with perfusion and hospital policies and procedures is monitored and reported daily by the Risk and Patient Safety Coordinator through the Dignity Health iVOS event reporting system. (11/1/2015 and Ongoing)

Monitoring Results:

There have been no known incidents, events or complaints related to the lack of compliance to pertinent (applicable to perfusionists) hospital or perfusion policies and procedures since the date of this event in 2015.

Equipment

Leadership Accountability: Medical Director, Cardiothoracic Surgery

Immediate and Systemic Corrective Actions:

1. The affected Sorin S5 cardiopulmonary bypass machine was immediately removed from service and sequestered pending investigation. (11/04/2015)
2. ECRI Institute was contracted to conduct an independent examination of the associated medical devices and to review this event. (11/17/2015)
3. Based on this report and the manufacturer's instructions for our Sorin S5 machine, only the manufacturer's brand of pump heads are exclusively used. (11/30/2015)
4. This Sorin S5 machine was thoroughly evaluated, tested and returned to service. (8/24/2016)
5. A Pump Failure Adverse Event Protocol was approved and implemented which outlined the action steps for Management of a Pump Failure. This was included in the in-services as noted above immediately following the event and again on 7/19/16 and 10/7/16.

Monitoring Plan:

1. Any use of Sorin S5 machine parts not listed on the manufacturer's guidelines and all pump failures were required to be reported to the Risk and Patient Safety Coordinator as well as the Medical Director for Cardiothoracic Surgery and the Chief Nurse Executive Officer through the Dignity Health iVOS event reporting system. (11/10/15 and Ongoing).
2. All significant quality and patient safety events (including any pump failures) are immediately reported to the Chief Nurse Executive Office, Chief Medical Officer, and Medical Director of Cardiothoracic Surgery by the Risk and Patient Safety Coordinator. They are addressed with an immediate case review and cause analysis, which are reported to the Medical Staff Patient Safety Committee, Medical Executive Committee and Quality Committee of the Community Board. (11/1/2015 and Ongoing)

Monitoring Results:

1. There have been no known incidents or events related to the Sorin S5 machine or any other medical devices used in our open heart procedures since the date of this event in 2015.
2. All preventive maintenance requirements have been completed on the Sorin S5 machine according to manufacturer's guidelines and to date only Sorin S5 pumps have been used for cardiovascular procedures since the date of this event in 2015.

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Title 22 California Code of Regulations, Section 70435: Cardiovascular operative services: A physician shall have overall responsibility for the service. This physician shall be certified or eligible for certification by the American Board of Thoracic Surgery or the American Board of Surgery with training and experience in cardiovascular surgery. He shall be responsible for implementing established policies and procedures and training and supervising the clinical perfusionists.

Oversight Accountability

Leadership Accountability: Medical Director, Cardiothoracic Surgery

Immediate and Systemic Corrective Actions:

1. At the time of this event, the perfusionist involved was removed from all cases involving the cardiopulmonary bypass machine pending investigation. (11/4/2015)
2. The perfusionist involved subsequently resigned from the contract company and all privileges were removed. (5/4/2016)
3. A pump failure protocol was updated and all perfusionists providing services were educated and evaluated for current competence. This was included in the in-services as noted above immediately following the event and again on 7/19/16 and 10/7/16.
4. A formal letter was sent from the President of St. John's Regional Medical Center to the Administrative leader of Vectra (Perfusion Contract) reaffirming discussions about expectations for all perfusionists. (10/5/16)
5. All four perfusionists currently providing services at St. John's Regional Medical Center have completed annual competencies on the following: (Most recent competency assessments 1/18/18)
   - Autotransfusion,
   - Platelet Gel,
   - Intra-Aortic Balloon Pump,
   - Off-Pump Coronary Artery Bypass, and
   - Coronary Artery Bypass Grafting / Valve Replacement.
6. The Medical Director for Cardiothoracic Surgery is Dr. James McPherson who is board certified in cardiac and thoracic surgery through 12/31/2019.
7. The approved and signed Medical Director contract accountabilities include, but are not limited to the following: (Contract signed initially 3/24/2016 and is valid through 4/1/2018. It is in the process of being renewed at this time.)
   - Provide medical direction for the day to day operations of the Cardiothoracic Surgery Program (Program);
   - Advise and assist in creating and implementing policies and procedures related to the Program;
   - Advise and assist in ensuring physician coverage for the Program;
   - Advise and assist in scheduling, coordinating and supervising the provision of medical and ancillary staff and services within the Program;
   - Assist in the continued development of an integrated comprehensive Program at the hospital;
   - Be responsible to Hospital Administration for the professional services and medical management of the Program and participate in management development programs;
   - Advise and assist Hospital in the development and implementation of an appropriate Quality Assessment and Improvement Program with respect to the Program and participate in such Program;

- Participate in such Hospital and Medical Staff committees as Hospital or Medical Staff may request;
- Work with Hospital administration in the timely planning of activities, including the annual development of Program objectives, operations budget and a capital equipment budget, and provide Hospital with ongoing appraisals of the strengths, weaknesses and overall quality of the Program;
- Fully cooperate with Hospital personnel assigned general administrative responsibilities for operation of the Program;
- Advise and assist in the organization and implementation of an effective Utilization Review Program for the Program and Hospital and perform utilization review services;
- Develop and review on-going training and continuing education programs for the Medical Staff, the nursing staff and other support personnel;
- Advise and assist Hospital in ensuring that the Program is operated in accordance with all requirements of the Joint Commission, all applicable licensing requirements, and all other relevant requirements promulgated by any federal, state, or local agency;
- Recommend to appropriate committees of the Medical Staff and/or Hospital Administration new or revised policies as needed; and
- Participate in developing and presenting programs pertinent to the Program for the community and as needed for Hospital/community relations.

Monitoring Plan:

1. The accountabilities of the Medical Director as outlined above are evaluated annually to determine compliance with these responsibilities. (Annually beginning in 2016)

Monitoring Results:

Based on the evaluations completed in 2016 and 2017, there have been no identified issues or opportunities for improvement in the Medical Director's evaluations.

<u>Contract</u>

Leadership Accountability: Chief Operating Officer

Immediate and Systemic Actions:

1. The contract in place at the time of this event which did not have an end date was amended to include an expiration date. (5/5/16)
2. The contract currently in effect was approved with an end of February, 2020. (2/21/18)

Monitoring Plan:

All opportunities for improvement are captured by assigned RN staff in the OR and reported to the Chief Nurse Executive Officer, the Medical Director of Cardiovascular Services and quarterly summary findings are presented to the Hospital Quality Committee, Medical Executive Committee and Quality Committee of the Community Board through minutes. A quarterly report is done with the following indicators. (2016 and Ongoing)

The indicators include these:

- Preventive maintenance on all perfusion equipment is done in a timely manner;
- Point of Care Testing is done and reported according to hospital policies and procedures;

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- National Patient Safety Goals affecting the perfusionists are in compliance;
- Infection prevention and control policies and procedures are met;
- Perfusionists arrive on time for procedures; and
- Dimensions of performance are consistently met. These include efficacy, appropriateness, availability, timeliness, effectiveness, continuity, safety, efficiency, respect and caring.

Monitoring Results:

Based on the annual evaluations, the perfusionists have been compliant with all of the metrics and the dimensions of performance were all scored excellent since the date of this event.

Gloria Gammage

Gloria Gammage, MSN, RN, Chief Nurse Executive Officer
Dignity Health St. John's Regional Medical Center