

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/16/2014
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 480002	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/01/2014
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NAME OF PROVIDER OR SUPPLIER GOV JUAN F LUIS HOSPITAL & MEDICAL CTR	STREET ADDRESS, CITY, STATE, ZIP CODE #4007 EST DIAMOND RUBY, CHRISTIANSTED ST CROIX, VI 00820
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A 000	INITIAL COMMENTS A full Medicare survey was conducted on July 28, 2014 through August 1, 2014 at the Governor Juan Luis Hospital. In addition, a complaint survey was also conducted based upon reported concerns. At the time of the survey, the hospital stated the census was 55.	A 000		
A 020	482.11 COMPLIANCE WITH LAWS Compliance with Federal, State and Local Laws This CONDITION is not met as evidenced by: Based on interview and record review the hospital has failed notify the Nuclear Regulatory Commission (NRC) of the current status of the hospital's Nuclear Medicine Program. Evidence includes the following: Review of E-mail correspondence between hospital administration SP #5 and CMS, revealed that on June 23, 2014, the NRC conducted a routine five year inspection of the hospital ' s Nuclear Medicine Lab. The hospital's Nuclear Medicine Program has been dormant since August 2013. One of the concerns relayed to the hospital during the NRC's inspection was that the NRC was not notified of the dormant status of the Nuclear Medicine Program. Chief Radiologist/Radiation Safety officer SP #23 confirmed this information in an interview on July 31, 2014, at approximately 9:00 a.m. stating the hospital had not met the requirement of reporting the status of the Nuclear Medicine Program to the NRC because the hospital's Radiation Safety Committee had yet to meet to determine what status of dormancy of this program to report to	A 020		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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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. (See instructions.) Except for nursing homes, the findings stated 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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A 020	Continued From page 1 the NRC. Review of Radiation Safety Committee meeting minutes dated November 20, 2013, listed reporting the status of the Nuclear Medicine Lab an action item with a due date of November 20, 2013. Issues included "different options of dormancy in order to preserve the NRC license for operating the Nuclear Medicine Lab." No decision was made and the meeting minutes categorize the status of this action item as TBD (To Be Determined).	A 020			
A 043	482.12 GOVERNING BODY There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ... This CONDITION is not met as evidenced by: Based on review of hospital documents and interviews, this hospital failed to have an organized and effective Governing Body responsible for the operation of the hospital. The statute of the Virgin Islands provides that the authority to supervise the day-to-day operations of the hospital is delegated from the Territorial Board (TB) to the St. Croix District Board (SCDB) for as long as the district board exists. See 19 V.I.C. §242(b) and 244(k). The SCDB is comprised of nine members. Five members shall constitute a quorum. See 19 V.I.C. §243(g). However, due to insufficient numbers of SCDB members, it is inactive. Therefore, the TB had	A 043			

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A 043	<p>Continued From page 2</p> <p>assumed the Governing Body functions for the hospital.</p> <p>Review of the TB meeting minutes from January 10, 2014, to April 2, 2014, revealed that the TB conducts its meeting to provide oversight on two (2) territorial hospitals at the same time. The leadership of both hospitals provides reports and discusses hospital issues during the duration of the TB meeting. There was no indication that the TB was functioning solely as the Governing Body of SCDB. This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014.</p> <p>Review of the TB meeting minutes from January 10, 2014, to April 2, 2014, revealed that there were no quality of care issues (See Tag A-0049), or quality assessment and performance reports discussed during the meetings (See Tag A-0309). This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014.</p> <p>Additionally, the hospital failed to have an effective Governing Body that ensured the Systems Improvement Agreement, signed in 2011 was honored and compliance was achieved and sustained. Evidence includes the following:</p> <p>Please refer to the following:</p> <p>42 CFR 482.12- Governing Body</p> <p>42 CFR 482.13- Patient Rights</p> <p>42 CFR 482.22 - Medical Staff</p>	A 043			

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A 043	Continued From page 3 42 CFR 482.23- Nursing Services 42 CFR 482-24- Medical Records 42 CFR 482.42- Infection Control 42 CFR 482.52- Anesthesia Services The continued non-compliance and the cumulative effect of the lack of oversight and actions resulted in the Governing Body's ineffectiveness for the conduct of the hospital.	A 043			
A 046	482.12(a)(2) MEDICAL STAFF - APPOINTMENTS [The governing body must] appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. This STANDARD is not met as evidenced by: Based upon review of hospital Bylaws and review of personnel files, the hospital failed to appoint members to the Medical Staff through the Governing Body. Evidence includes the following: Review of the hospital Medical Staff Bylaws revealed on Section 10 that "temporary privileges may be granted by the CEO acting on behalf of the board, upon written concurrence of the chairperson of the service in which privileges will be exercised, or by the President of the Medical Staff" Review of six (6) credential files, SP #30, SP	A 046			

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A 046	Continued From page 4 #34, SP #35, SP #36, SP #37 and SP #38, revealed that the privileges of these physicians to practice at this hospital were awarded by the Chief Executive Officer (Interim), Chief Medical Officer (Interim), and the Chief of Service. These appointments were not brought up to the governing body for approval before these physicians started practicing at the hospital.	A 046			
A 049	Please refer to A-0341. 482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based upon medical records review and interviews, the hospital failed to achieve and sustain compliance, and the Medical Staff of the hospital was not accountable to the Governing Body. The Governing Body failed to ensure that the Medical Staff provided quality care to patients in that numerous cases that lead to patient harm were not brought to the attention of the Governing Board. Consequently, the Governing Body was unable to act upon these issues to ensure the quality of care provided to patients. This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014. This practice poses a high potential for harm to patients admitted to this hospital. Quality of care issues that resulted in patient harm include but are not limited to:	A 049			

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A 049	Continued From page 5 On July 28, 2014, an elderly patient, Patient #4 was noted during rounds with staff to have a large hematoma of the center of the forehead. The patient alleged to have suffered an unwitnessed fall the evening before based upon statements from the patient. The physician assistant (PA) noted only no headache, no dizziness and no neurological findings and did not order close monitoring of neurologic status. No medical interventions were provided until the patient's condition deteriorated. The patient was transferred to the intensive care unit, was intubated and had less than a 2% chance of survival and would likely remain in a vegetative state according to physician documentation if the patient survived the ordeal. On June 17, 2014, Patient #3 presented to the emergency department and diagnosed with right pleural effusion. The x-ray showed "an almost complete opacification of the right hemothorax." Although the physical assessments, findings, and nurses notes were inconsistent with the imaging studies, the physician inserted a chest tube on the left side of the chest inspite of the patient telling the physician that the procedure was being done on the wrong side of the chest. Please refer to A-0450. On June 4, 2014, a newborn, Patient #9, was delivered by emergent vacuum delivery due to signs of fetal distress. The baby sustained a subgleal bleed, a known potential complication of vacuum birth delivery. The newborn died within hours of birth. On May 19, 2014, a patient previously diagnosed	A 049			

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A 049	<p>Continued From page 6</p> <p>with left frontal meningioma arrived in the emergency department and required intubation. During intubation, two (2) front teeth were dislodged from Patient #27 who was then transferred off island for treatment.</p> <p>On May 10, 2014, Patient #26 presented to the emergency department due to seizure and was admitted to the hospital for treatment. The patient had a fall from his bed on May 11, 2014, and sustained laceration on the eyebrow.</p> <p>On April 27, 2014, Patient # 25 presented to the emergency department at 1:34 p.m., with complaints of insidious onset of left chest pain and epigastric pain while lying down. The patient was discharged at 8:10 p.m., April 27, 2014. The patient was brought back to the hospital by ambulance, in full code 72-hours later, April 29, 2014, at 10:51 a.m and expired.</p> <p>On April 14, 2014, it was reported to CMS that hospital staff threw out the remains of a 22 week fetus either in the laundry or rubbish.</p> <p>On April 10, 2014, a newborn infant was born via caesarian section. The baby was admitted to Neonatal Intensive Care Unit due to hypoglycemia and an intravenous infusion was started. The patient received intravenous fluids where the antibiotic, gentamycin, may have infiltrated and caused ischemia (vascular compromise) to the right forearm and fingers. The baby, Patient #6, was transferred to an off island hospital to the care of a pediatric vascular surgeon.</p> <p>On April 3, 2014, Patient #8 presented to the emergency department and was diagnosed with</p>	A 049			

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A 049	<p>Continued From page 7</p> <p>cholelithiasis and cholecystitis. She was admitted for laparoscopic cholecystectomy and sustained a bile duct injury. She was transferred to an off island hospital for further care.</p> <p>Telephone interview with the Chairman of the Medical Staff Quality Committee (MSQC) on August 1, 2014, at 11:30 a.m., revealed that cases which results in patient harm are reviewed by the committee. Upon completion of review, it was sent to the Medical Executive Committee (MEC) for action. There was no communication back to the MSQC from the MEC regarding disposition of cases.</p> <p>Interview with the Chairman of the MEC on August 1, 2014, at 1:40 p.m. revealed that when cases are received from the MSQC, the committee decides what action to take with the case. The Chairman was asked what was done with the case where a patient sustained two (2) dislodged teeth. The Chairman informed the surveyor that the case was reviewed and closed because the hospital offered financial payment for the repair of the dislodged teeth. The Chairman was asked whether quality of care issues are brought up to the attention of the Governing Body. The Chairman stated that no quality of care issues are brought up to the attention of the Governing Body.</p> <p>Additional quality of care issues that resulted in patient harm that occurred in 2013 include:</p> <p>February 2013, a pregnant patient presented seven (7) times to the Emergency Department within a period of five (5) weeks. Despite the documented allergic reaction to specific medications, the medical staff ordered and the</p>	A 049			

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A 049	<p>Continued From page 8</p> <p>patient received the medication that she was known to be allergic to.</p> <p>March 2013, a patient was admitted to the hospital due to right upper quadrant abdominal pain. An endoscopic retrograde cholangiopancreatogram was attempted and failed which resulted in bile duct injury and bile leak. The patient was transferred to an off island hospital for care.</p> <p>April 2013, a patient with abdominal pain presented to the emergency department; was admitted on the third visit. An abdominal exploratory laparoscopy was performed and showed perforated gangrenous appendix with multiple abdominal abscess.</p> <p>April 2013, a patient had an abdominal exploratory laparoscopy and sustained a ruptured bladder.</p> <p>September 2013, patient was admitted due to abdominal pain and was diagnosed with acute cholecystitis. The history and physical examination pre-operatively was incomplete and failed to assess the comorbidities of the patient which include cardiac valve disease, diabetes and hypertension. Immediately post-operatively, the patient desaturated and became unresponsive. The patient was subsequently found to have critical aortic stenosis.</p> <p>October 2013, a patient was admitted to the hospital due to intractable abdominal pain and exploratory laparoscopy was performed. Patient was discharged home but returned to the emergency department and diagnosed with peritonitis. An exploratory laparoscopy was</p>	A 049			

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A 049	Continued From page 9 performed and found small bowel contents in the abdomen with a small perforation. The patient died of overwhelming sepsis. Also, in October 2013, there was a case where there was a delay in the physician arriving to the Emergency Department where the patient was diagnosed with ruptured ectopic (tubal) pregnancy and another case where the operating room staff were not fully prepared. The surgical team lacked cross training with the procedure that was being done for the first time at the hospital, experienced multiple equipment failures and there was missing equipment which resulted with the surgical case taking eight (8) hours. These cases, although reviewed through various stages by the Medical staff, the Medical Staff failed to present these significant patient care issues to the TB, so the TB could appropriately act on these quality of care issues as the Governing Body of the ospital.	A 049			
A 050	482.12(a)(6) MEDICAL STAFF - SELECTION CRITERIA [The governing body must] ensure that criteria for selection are individual character, competence, training, experience, and judgement. This STANDARD is not met as evidenced by: Based upon record reviews, review of credential files and confirmation with hospital staff, the hospital failed to grant privileges to Medical Staff according to their competencies. Evidence includes the following: Review of ten (10) credential files of physicians SP #25, SP #27, SP #32, SP #34,	A 050			

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A 050	<p>Continued From page 10</p> <p>SP #39, SP #36, SP #30, SP #35, SP #42 and SP #38, granted privileges to practice at this hospital, revealed that the governing body failed to ensure that all practitioners who provide a medical level of care and/or conduct surgical procedures in the hospital were granted only those specific privileges that practitioners have current and proven competence to do and that the hospital have the requisite support staff, adequate equipments, and supplies for such procedures to be performed.</p> <p>Review of the ten (10) credential files revealed that the physicians were granted generic core privileges for a service line, e.g., anesthesiology, urology, surgery. For example, "Management of patients of all ages except as specifically excluded from practice, rendered unconscious or insensible to pain and emotional stress during surgical, obstetrical and certain medical procedures; including preoperative, intraoperative and post-operative evaluation and treatment; the support of life functions and vital organs under stress of anesthetic, surgical and other medical procedures; medical management and consultation, pain management and critical care medicine, direct resuscitation in the care of patients with cardiac or respiratory emergencies, including the need for artificial ventilation, pulmonary care, supervision of patients in post-anesthesia care units and critically ill patients in special care units."</p> <p>It cannot be assumed that a practitioner can perform every task/activity/privilege listed/specified for the applicable category of practitioner. The individual practitioner's ability to</p>	A 050			

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A 050	Continued From page 11 perform each task/activity/privilege must be assessed and not assumed. If the practitioner is not competent to perform one or more tasks/activities/privileges, the list of privileges is modified for that practitioner. None of the core privileges were amended to reflect the physician's current area of expertise and that the hospital have adequate resources to support. Hospitals must assure that practitioners are competent to perform all granted privileges. This was verified by the Chairman of the Credentialing Committee during the interview on July 29, 2014, at 10:50 a.m. The Chairman informed the surveyor that the core privileges are being revised to reflect specific procedures and skill sets. However, this revised privileging format was not in place at the time of the survey.	A 050			
A 073	482.12(d) INSTITUTIONAL PLAN AND BUDGET The institution must have an overall institutional plan that meets the following conditions: (1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles. (2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense. (3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable. (4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is	A 073			

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A 073	Continued From page 12 established, in accordance with section 1122(g) (1) of the Act, by the State in which the hospital is located) that relates to any of the following: (i) Acquisition of land; (ii) Improvement of land, buildings, and equipment; or (iii) The replacement, modernization, and expansion of buildings and equipment. This STANDARD is not met as evidenced by: Based upon document review and interview, the hospital failed to develop an annual budget in accordance with professional standards. Evidence includes the following: Review of the hospital's institutional plan and budget revealed that it was not prepared in accordance with accepted accounting principles and did not include capital expenditures for at least a 3-year period. This was verified by the Interim Chief Financial Officer during the review of the institutional plan and budget at his office on July 30, 2014.	A 073			
A 084	482.12(e)(1) CONTRACTED SERVICES The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based upon documents review, the hospital failed to achieve and sustain compliance since 2012 in order to evaluate the quality of the services provided by contractors. Evidence includes the following: Nine (9) contracted services were reviewed.	A 084			

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A 084	Continued From page 13 (Medical Imaging, Inc. - CT/MRI, Medical Imaging, Inc. - Nuclear Medicine, Nationwide Lab Services, Creative Testing Solutions, Amerisource Bergin Drug Corpotation, Cardiac Therapies and Vascular Solution, Matlock Endoscopic Repairs, Johnson and Johnson, Island Airlines). Based upon the review, only one (1) of the nine (9) (Amerisource Bergin Drug Corportaiion) of these contracted services had an evaluation completed by the pharmacist in-charge. Review of the Territorial Board (TB) meeting minutes from January 10, 2014, to April 2, 2014, revealed that no evaluation of the services provided by contractors of services to the hospital. Consequently, the TB failed to ensure that the services provided by contractors meet the needs of the patient and provided in a safe and effective manner, and meets nationally accepted standards of care.	A 084			
A 115	482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based upon observations, medical records and documents review and interviews, the hospital failed to achieve and sustain compliance to ensure the rights of patients were promoted and that their environment was safe. Evidence includes the following. 1. The hospital failed to ensure that patients received a written notice to fully inform them of the results from their grievances and the hospital	A 115			

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A 115	Continued From page 14 failed to appropriately identify what constitutes a grievance. Please refer to A-0123. 2. The hospital failed to ensure that patients and families were able to participate in the development of their care plans. Please refer to A-0130. 3. The hospital failed to ensure that patients were able to make informed decisions regarding their care. Please refer to A-0131. 4. The hospital failed to ensure patients were afforded full privacy during care. Please refer to A-0143. 5. The hospital failed to provide care in a safe environment. Please refer to A-0144. 6. The hospital failed to ensure all patients were free from confinement. Please refer to A-0145 7. The hospital failed to have a mechanism in place to protect the confidentiality of medical records during construction. Please refer to A-0147. 8. The hospital failed to ensure patients were free from physical restraints without an assessment to clinically justify their use. Please refer to A-0154. 9. The hospital failed to ensure patients were free from chemical restraints without an assessment to clinically justify their use. Please refer to A-0160. 10. The hospital failed to support equal visitation rights to all patients. Please refer to A-0217	A 115			

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A 123	<p>482.13(a)(2)(iii) PATIENT RIGHTS: NOTICE OF GRIEVANCE DECISION</p> <p>At a minimum: In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.</p> <p>This STANDARD is not met as evidenced by: Based on interviews and document review, the hospital failed to achieve and sustain compliance since 2012 related to patient grievances. The hospital failed to properly identify grievances and ensure the grievance resolution notice fully informed the complainant of the investigation outcome for each grievance.</p> <p>A review of the grievance log was conducted on July 31, 2014. The log included a grievance with two concerns forwarded by the mother of Patient #10. A notice of the grievance outcome, informing the complainant of the results of the hospital's investigation, was provided by representatives of the Patient Advocate department. This closure notice included a description of two of the grievance complaints including an unwillingness to pay a hospital bill and an allegation that the child of the complainant was misdiagnosed. The notice addressed the hospital bill but did not include the resolution for the second concern brought forward to the hospital.</p> <p>An interview with the Chair of the grievance committee, SP #16, was conducted on July 31, 2014, at approximately 3:20 p.m. The Chair acknowledged that the notice did not contain</p>	A 123			

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A 123	Continued From page 16 resolution information for all of the allegations. The facility failed to ensure the resolution notice fully informed the complainant of the investigation outcome. On July 31, 2014, at approximately 1:45 p.m., an interview was conducted with two Patient Advocate staff members, SP #14 and SP #15, accompanied by the SP #8 regarding policies and practices for grievance management. The Patient Advocate staff members were given scenarios in which patient's family members forwarded concerns that call bells were not being answered to them in writing by placing written notices under their office doors. The staff members stated concerns forwarded to them in this manner would be treated as complaints and not as grievances. The staff members were asked three times if the written concerns meet the criteria of complaint or grievance. Each time the staff members agreed that the written concerns would be treated as complaints and not as grievances. Complaints are not processed through the hospital's grievance committee. A grievance is defined in the facility's Policy and Procedure entitled "Patient Advocate Grievance Policy" with an effective date of February 12, 2013, as "A formal or informal written or verbal complaint regarding that patient's care." A subsequent interview was held with the Grievance Committee Chair on August 1, 2014, at approximately 10:40 a.m., during which the Chair stated that the staff members should have known that all written complaints are grievances.	A 123			
A 130	482.13(b)(1) PATIENT RIGHTS:PARTICIPATION	A 130			

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A 130	<p>Continued From page 17 IN CARE PLANNING</p> <p>The patient has the right to participate in the development and implementation of his or her plan of care.</p> <p>This STANDARD is not met as evidenced by: Based on observations, interviews and documents review, the hospital failed to promote and preserve all patients and families rights to participate in care plan development. Evidence includes the following:</p> <p>1. On July 28, 2014, a tour of the medical and surgical inpatient units began at approximately 10:50 a.m., accompanied by the SP #12 and SP #17.</p> <p>Patient #11 was observed to be lying in bed. Signage on the door indicated the patient to be on contact precautions (indicating the patient needed to be isolated from others to prevent transmission of infection) and fall precautions.</p> <p>The patient expressed frustration that the patient was unaware of what was taking place to prepare for discharge. The patient stated that his needs were verbalized but that no response was received. On August 1, 2014, at 9:37 a.m., the patient was again observed to be isolated in his room. The patient stated there have been no discussions with him regarding planning of his care or discharge planning. The patient stated he was provided with no assistance for discharge planning and that he had asked several times about equipment needed for his return home.</p> <p>When asked if he was invited to participate in decisions about his care and if he was informed</p>	A 130			

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A 130	<p>Continued From page 18</p> <p>about his isolation status, the patient became emotional and stated "I don't know if it's this room or this floor. I don't know why people have to wear the gown. The patient stated that he only knew that he was on fall precautions because he asked what the "yellow band" was for. The patient again expressed frustration, stated "I've been here for three weeks now."</p> <p>2. On July 28, 2014, a tour of the medical and surgical inpatient units began approximately 10:50 a.m., an observation of a yellow star was noted to be next to the door on the name indicator slots. Patient #12 was observed to be resting in bed. The Unit Manager explained that the yellow star indicated fall precautions.</p> <p>On July 29, 2014, at approximately 11:25 a.m., the patient was observed in his bed. During a brief interview with the patient, it was observed that the patient did not have a yellow arm band and was unaware that he had been determined to be at risk for falls. The Certified Medical Assistant, SP #18, assigned to the patient's care, was interviewed regarding the yellow star with an "A" in the center near Patient 25's doorway. The staff person stated that the patient had a history of falling and the staff would assist him to bathe or to the commode. When asked if the patient knew he was on fall precautions the staff member stated yes. The staff member was informed that the patient was in fact not aware of this designation.</p> <p>A review of the facility's Policy and Procedure (P&P) for Falls, the document instructs that patients will have a yellow star on the door, a yellow arm band and an indicator on the patients clinical record.</p>	A 130			

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A 130	Continued From page 19 Upon interview on August 1, 2014, at approximately 9:23 a.m., the patient had not been invited to participate in developing the plan of care, and the patient was unaware of his right to participate. 3. On August 1, 2014, at approximately 09:25 a.m., Patient #13 was observed in bed, accompanied by a close family member. When asked if the patient or family were invited to participate in Care Plan development, both stated "no." The family member stated being present when the discharge planning staff came to the patient's room but stated that the Social Worker only asked how many steps were in the patient's home. The family member stated there has been no discussion regarding discharge planning with the patient or family members. During an interview with the Unit Manager on August 1, 2014, at approximately 8:12 a.m., the staff member was asked about Care Plan development. The staff member stated that the Care Plans were developed by the nurses and that neither patients nor their families were invited to participate in the development of the Care Plans. As such, the facility failed to ensure the patients rights to participate in decisions regarding their care.	A 130			
A 131	482.13(b)(2) PATIENT RIGHTS: INFORMED CONSENT The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his	A 131			

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A 131	<p>Continued From page 20</p> <p>or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.</p> <p>This STANDARD is not met as evidenced by: Based on observations, interviews and documents review, the hospital failed to ensure each patient's rights to be fully informed of their health status and to make fully informed healthcare decisions were preserved and promoted. Evidence includes the following:</p> <p>1. On July 28, 2014, Patient #11 was observed to be lying in bed on the medical unit. Signage on the door indicated the patient to be on contact precautions (indicating the patient needed to be isolated from others to prevent transmission of infection) and fall precautions. The patient expressed frustration, stating he was unaware of what was taking place to prepare him for discharge. The patient stated that his needs for certain equipment were verbalized but that no response was received. The patient stated he lives alone and needed equipment to assist with Activities of Daily Living.</p> <p>On August 1, 2014, at 9:37 a.m., the patient was again observed to be isolated in his room. When asked if he was informed about his isolation status, the patient became emotional and stated "I don't know if it's this room or this floor. I don't know why people have to wear the gown. The patient stated that he only knew that he was on fall precautions because he asked what the "yellow band" was for. The patient again expressed frustration stated "I've been here for</p>	A 131			

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A 131	Continued From page 21 three weeks now." A review of the clinical record shows the patient to have been admitted on July 16, 2014, the patient had an amputation of the left lower leg.	A 131			
A 143	2. The clinical record for Patient #12 was reviewed on July 29, 2014, at 10:30 a.m.. The patient was admitted on July 27, 2014 for surgical repair for gallstones. A document entitled "Consent to Administration of Anesthesia" was found in the record. The document's signature page does not include the patient's printed name, date or time. The patient's Informed Consent form was not fully completed. 482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY The patient has the right to personal privacy. This STANDARD is not met as evidenced by: Based on observation and interview, the hospital failed to ensure Patient # 12' s privacy following a medical procedure. Evidence includes the following: On July 29, 2014, at approximately 11:10 a.m., the nurse was observed to complete a urinary catheterization for Patient #12. To complete the procedure, the door was closed and the patient was exposed from the chest down. Following the catheterization, the nurse opened the door and began to wash her hands. The patient was in the bed nearest the door and was visible to staff and visitors present in the hallway. The nurse did not cover the patient to preserve privacy. The SP #19 was asked about the exposure and confirmed that she should have	A 143			

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A 143	Continued From page 22 protected the privacy of the patient, stating that typically she would have pulled the privacy curtain, but that it was missing. When the patient was asked if being exposed concerned him, the patient stated the nurse "should have thought of it."	A 143			
A 144	482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on record review and interview the hospital failed to assure a safe environment for patient care by not preventing a situation where the operating room was potentially exposed to ionizing x-ray radiation. Evidence includes the following: 1. Interview with the Director of Radiology on July 30, 2014, at 09:15 a.m., and review on July 30, 2014, at 13:50 p.m., of the incident report filed with the SP #6 detailed the following event: The key allowing activation of the operating room's C-Arm Mobile fluoroscopy unit in the operating room had been lost. On September 4, 2013, SP #24 told the Director of Radiology the C-Arm could be activated by using a knife to shim the lock. The Director of Radiology told SP #24 not to attempt to activate the machine. On September 5, 2013, the Director of Radiology was notified that the C-Arm had been activated and was potentially exposing patients and staff in the operating room area to ionizing radiation. The Director went to the operating	A 144			

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A 144	<p>Continued From page 23</p> <p>room and found the C-Arm activated. SP #24 later acknowledged improperly activating the machine. These events were confirmed by the hospital Risk Manager on July 30, 2014, at 13:50 p.m., and the Chief Radiologist on July 31, 2014, at 08:30 a.m.</p> <p>Based upon medical record review and interview the hospital failed to have accurate and legible medical entries to assure safe appropriate care was provided, failed to appropriately conduct a time out process prior to the procedure in accordance with standard of practice and failed to listen to the patient when told the procedure was being conducted on the wrong side of the chest cavity. Evidence includes the following:</p> <p>2. Patient #3 presented to the Emergency Department (ED) on June 17, 2014, with a chief complaint of shortness of breath. Review of the medical record identified that the patient was seen in room 17 but the time recorded that the patient was seen was crossed out and illegible on the Emergency Physicians Record. The patient was described as alert, coherent and oriented.</p> <p>By history, the patient had diminished right breath hemithorax (a collection of blood in the space between the chest wall and the lung-the pleural cavity). A chest computed tomography scan (CT), chest x-ray and surgical consult were ordered.</p> <p>The physician in the Emergency Department interpreted the chest x-ray taken and documented his reading of the x-ray film in the section of the order sheet that describes the results from a</p>	A 144			

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A 144	<p>Continued From page 24</p> <p>chest x-ray. He placed the question mark symbol and "left (L) pleural effusion 100%." There is nothing to elaborate what the question mark meant nor is this accepted medical documentation.</p> <p>On the same page, there is a medical entry that indicated "CT R (right) pleural effusion" which is the opposite laterality from the earlier entry. Under the section titled " Clinical Impression" is an abbreviation that identified the laterality but had been written over. The documentation indicated right (r) pleural effusion.</p> <p>Review of the practioners verification and time out process form noted the procedure was documented as "drainage of left chest" at 11:50 p.m. but the time out section to verify laterality, surgical site markings and other necessary medical information was blank. The form that authorized SP #30 to perform the procedure indicated that the diagnosis was "left pleural effusion" but the patient never initialed the form as understanding the procedure at line #3 of the form. The right side was the correct side for the procedure.</p> <p>Medical Provider note of June 18, 2014, written at 10:14 p.m., noted that SP #30 was called to the ED to evaluate a patient with left sided effusion. After arriving in the ED, the chest x-ray was examined and a 22 Fr (French) chest tube was placed for drainage without any fluid return. After re-examining the chest x-ray, it was noted that the left marker was placed on the patient's right and the x-ray was flipped to proper markings.</p> <p>Once the error was identified, the patient had another drainage tube placed on the appropriate</p>	A 144			

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A 144	Continued From page 25 right side of the chest which then drained about 620 ml (milliliters) of bloody drainage. The patient was then transferred to the Intensive Care Unit and left chest tube was discontinued. An investigation was conducted by hospital staff and notation in the record included SP #30 stating, " I should have listened to the patient." These findings were confirmed with hospital staff. Please refer to A-0450.	A 144			
A 145	> 482.13(c)(3) PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based upon records review, observations and interviews, the hospital failed to ensure that all patients are free from all forms of abuse in that during an observation of care provision in the emergency department (ED) on July 30, 2014, at 3:00 PM, Patient #29 approached the nurses' station asking for his clothes and belongings so that he could leave. Review of the patient's medical record showed that this patient was awaiting transfer to a hospital in St. Thomas, V.I. for inpatient psychiatric treatment. Review of the physician's order revealed that the psychiatrist ordered on July 30 2014, at 09:00 a.m., the following: "psychiatric observation, no family visits, every 15 minutes suicide watch." The ED nursing supervisor informed the surveyor	A 145			

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A 145	<p>Continued From page 26</p> <p>that this patient is on "72-hour hold," so the patient cannot leave. The medical record revealed a form titled "Application for Emergency Psychiatric Hold" which was dated but not timed. The form was not fully completed since there was no administrative approval to indicate whether the application was approved or denied. Since there were no time when the application was initially filled out, no time when it was notarized and the other required section for approval/denial was not completed, it could not be determined when the 72-hour hold started or when it will end. The surveyor asked the ED supervisor when the 72-hour psychiatric hold began or when it will end. The ED supervisor stated that the 72-hour started when the patient was admitted to the ED and will end 72-hours later. Since the "Application for Emergency Psychiatric Hold" was not properly completed, the patient was subjected to unreasonable confinement when his request to leave was denied.</p> <p>The "Application for Emergency Psychiatric Hold" for Patient # 29 was shown to the treating psychiatrist during the interview in the ED on July 30, 2014. The surveyor was informed that she had nothing to do with the completion of that form.</p> <p>The patient was interviewed by the surveyor on August 1, 2014. The patient informed the surveyor that he eloped because "they cut off my contact with my family who have been my support through all these years. I cannot even text my girlfriend who's sick and nobody is caring for her since I'm here." The surveyor asked the patient if he was informed of the reasons of the visitation restrictions. The patient stated that "they didn't tell me anything. They just took everything from</p>	A 145			

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A 145	Continued From page 27 me including my phone, and I cannot make any calls." The patient was also asked if he was informed of the reasons he was being held in the ED. He informed the surveyor that "they are supposed to send me to St. Thomas but they are not doing anything, so I don't know. "	A 145			
A 147	482.13(d)(1) PATIENT RIGHTS: CONFIDENTIALITY OF RECORDS The patient has the right to the confidentiality of his or her clinical records. This STANDARD is not met as evidenced by: Based on observation and staff interview, the hospital failed to ensure that stored medical records were keep safe from unauthorized access. Evidence includes the following: During the interview with the Medical Records Supervisor on July 30, 2014, at 2:15 p.m., SP #26 reported that the Medical Records room was currently undergoing an OSHA required decontamination of mold and dust. SP #26 said that three workers were in the room from 8 a.m. until 5 p.m. wiping down the open shelving. When questioned regarding maintaining the security of the medical records, SP #26 stated that she and the staff were "spot-checking" them. At 2:25 p.m., three workers were observed seated at a work table eating lunch. . There were no hospital staff present to ensure that the security of the medical records were being maintained. The hospital failed to implement procedures to protect stored patient information from unauthorized disclosures. Please refer to A-0441.	A 147			
A 154	482.13(e) USE OF RESTRAINT OR SECLUSION	A 154			

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A 154	Continued From page 28 Patient Rights: Restraint or Seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. This STANDARD is not met as evidenced by: Based upon medical records review, implementation of the hospital restraint policy and interviews, the hospital failed to adhere to the revised policies for restraint use for 2 of 2 patients. The hospital failed to achieve and sustain compliance with appropriate restraint use since 2012. Evidence includes the following: Medical record review of Patient #1 revealed presentation to the Emergency Department on July 28, 2014, via ambulance at 2055 hours after being assessed by Emergency Medical Technicians with obvious respiratory distress. Documentation revealed the patient was not breathing independently, required cardiopulmonary resuscitation and was intubated. Additional documentation on the Emergency Physician Record indicated the patient's pupils were fixed and the patient was "unresponsive." The patient was transferred to the Intensive Care Unit on July 28, 2014 at 2145 hours. Review of the physicians orders noted on July 28, 2014, at 2230 hours, an order was written for	A 154			

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A 154	<p>Continued From page 29</p> <p>wrist restraints. Review of the seclusion/restraint order sheet identified the behaviors that indicated clinical justification for the use of restraints was "attempting to remove medical necessary device" such as respiratory device.</p> <p>Under the section for the least restrictive measures that were attempted was documented "patient on vent" and response to less restrictive measures was documented as "n/a" (not applicable).</p> <p>Notations on the History and Physical dated July 28, 2014, recorded the patient was "unresponsive and intubated." On July 29, 2014, Code Blue (cardiac arrest) was called and the patient expired at 0559 hours.</p> <p>During an interview with SP #8 and SP #9 on July 31, 2014, at 9:45 a.m., nursing staff confirmed that the use of the physical restraints was only because the patient was on a ventilator. There was no assessment or evidence that the comatose patient had moved or had any autonomic reactions indicating that s/he was attempting to remove the device. It was further stated that patients that who are dependent on the use of a ventilator do not automatically require the use of physical restraints without clinical assessments.</p> <p>The facility failed to follow their policy related to the use of physical restraints and to implement and sustain corrective actions developed in the Plan of Correction from 2012. Noted on page 5 of the restraint policy, the expectations for assessment and attempts of the least restrictive</p>	A 154			

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A 154	<p>Continued From page 30 restraint use is detailed.</p> <p>Review of the Emergency Room Record for Patient #2 revealed the patient presented on July 5, 2014, in respiratory distress at 1343 hours. The patient was transferred to the Intensive Care Unit (ICU) for management and reversal of pneumonia and respiratory distress.</p> <p>Patent was on BiPap (Bilevel positive air pressure) and on July 13, 2014, at 0845 hours, the patient was intubated. Rapid changes in blood pressure reading , agonal breathing and no palpable pulse resulted with a Code Blue being initiated and patient pronounced dead at 2009 hours.</p> <p>Review of the restraint and seclusion order sheet initiated by the physician noted on July 13, 2014, at 0900 hours, fifteen minutes after being intubated, the identified the behaviors that clinically justified the use of the restraint as "interfering with medical devices and treatment and attempting to remove medically necessary devices." Further review of notes indicate response to less restrictive measures attempted was "verbal intervention" and the response was "unsuccessful."</p> <p>During an interview of July 31, 2014, at 9:35 a.m., SP #2 was unable to produce evidence of the patient attempting to interfere with treatment and remove respiratory devices nor any redirection provided. There was no assessment nor evidence of the clinical justification or any less restrictive interventions that had been attempted.</p>	A 154			

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A 160 A 160	Continued From page 31 482.13(e)(1)(i)(B) PATIENT RIGHTS: RESTRAINT OR SECLUSION [A restraint is-] (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. This STANDARD is not met as evidenced by: Based upon record review and interview, the hospital failed to ensure patients are free from chemical restraints, and failed to follow their policy for chemical restraint use. Specifically, there was no clinical justification for the use of an antipsychotic for Patient #8. Evidence includes the following: Medical record review for Patient #4 was reviewed on July 28, 2014. By history and physical documentation, the patient was admitted on July 27, 2014, with diagnoses that included anxiety for which an order for Ativan 1 milligram (mg) intravenous (IV) every 8 hours as needed was written at 1447 hours. There was no clinical indication as to why the dosage was ordered IV rather than orally. IV use is generally used for sedation. Later on July 27, 2014, at 1608 hours, in addition to the Ativan order, Haldol 0.5 mg was ordered. There was no indication of the need for the use of Haldol documented in the medical record. This medication is classified as an antipsychotic used to treat acute or chronic psychosis (abnormal condition of the mind.) Patient #4 had no	A 160 A 160			

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A 160	<p>Continued From page 32</p> <p>documented history or schizophrenia or psychosis.</p> <p>Noted in the physicians orders of July 28, 2014, at 1805 hours, was an order to increase the "Haldol 0.5 mg to bid" (twice a day) without any clinical justification that warranted justified the increased dosage if Haldol.</p> <p>Review of the care plan found no behaviors were described that would indicate a clinical need for the use of the antipsychotic Haldol nor indication of escalating behaviors that warranted an increase in the dose.</p> <p>In addition, a review of the nurses notes found no behaviors were described to support the use of the anitpsychotic other than a note on July 28, 2014, at 1529 hours, that "pt continually getting OOB." (out of bed) Several hours later, the Haldol was increased. "Getting OOB" is not an appropriate clinical indicator for the use of an antipsychotic.</p> <p>Although the hospital had revised their policy for restraint use and included an accurate definition of a chemical restraint, the hospital failed to implement their policy. Additionally, the policy addressed the assessment and documentation of the least restrictive interventions, which were not performed in accordance with hospital policy.</p> <p>The hospital failed to implement their policies and to assure that medications, (antipsychotics) were not used for staff convenience (patient repeatedly getting out of bed) and were only ordered with appropriate assessments and justification for their use. This practice was also in existence with the</p>	A 160			

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A 160	Continued From page 33 hospital being informed in 2013 of the inappropriate use of antipsychotics being used as a chemical restraint.	A 160			
A 217	482.13(h)(3), (h)(4) PATIENT VISITATION RIGHTS [A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements]: (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences. This STANDARD is not met as evidenced by: Based upon observation and interview, the hospital failed to promote equal visitation privileges, Evidence includes the following: The hospital failed to ensure that all patients exercise their visitation privileges in that during an observation of care provision in the emergency department (ED) on July 30, 2014, at 3:00 p.m., as Patient #29 approached the nurses' station asking for his clothes and belongings so that he could leave.	A 217			

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A 217	<p>Continued From page 34</p> <p>Review of the patient's medical record showed that this patient was awaiting transfer to a hospital in St. Thomas, V.I. for inpatient psychiatric treatment. The ED nursing supervisor informed the surveyor that this patient is on "72-hour hold," so the patient cannot leave.</p> <p>Review of the physician's order revealed that the psychiatrist ordered on July 30, 2014, at 09:00 a.m., the following: "psychiatric observation, no family visits, every 15 minutes suicide watch." Neither the physician order nor the physician progress notes showed any clinical justification for the visitation restriction. The treating psychiatrist informed the surveyor that she never provided any justification for visitation restrictions before during the interview in the ED on July 30, 2014. In spite of the hospital security officer in close proximity to the patient's room and the patient's room was in front of the nurses' station, the patient managed to elope. Police and hospital security searched for the patient who was found several hours later and returned to the ED.</p> <p>After the patient was returned on August 1, 2014, he was interviewed by the surveyor. The patient informed the surveyor that he eloped because "they cut off my contact with my family who have been my support through all these years. I cannot even text my girlfriend who's sick and nobody is caring for her since I'm here." The surveyor asked the patient if he was informed of the reasons of the visitation restrictions. The patient stated that "they didn't tell me anything. They just took everything from me including my phone, and I cannot make any calls."</p> <p>The hospital failed to follow and implement its</p>	A 217			

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A 217	Continued From page 35 own "Patient Visitation Policy." Review of the "Patient Visitation Policy" approved on May 30, 2013, by the Governing Body revealed that "All visitors designated by the patient (or Support person where appropriate) shall enjoy visitation privileges that are no more restrictive that those that immediate family members would enjoy." Further, the policy revealed that "The hospital may impose justified clinical restrictions on a patient's visitation rights. When restricting visitation rights, the Hospital shall explain to the patient (or Support person as applicable) the reasons for the restrictions or limitations on the patient's visitation rights and the hospital visitation policies are aimed at protecting the health and safety of all patients."	A 217			
A 263	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on review of hospital documents and	A 263			

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A 263	<p>Continued From page 36</p> <p>interviews, the Governing Body of this hospital failed to exercise its executive responsibilities to ensure that the quality assessment program track, analyze and put systems in place to reduce medical errors.</p> <p>The statute of the Virgin Islands provides that the authority to supervise the day-to-day operations of the hospital is delegated from the Territorial Board (TB) to the St. Croix District Board (SCDB) for as long as the district board exists. See 19 V.I.C. §242(b) and 244(k). The SCDB is comprised of nine members. Five members shall constitute a quorum. See 19 V.I.C. §243(g). However, due to insufficient numbers of SCDB members, it is inactive. Therefore, the TB had assumed the governing body functions for the hospital.</p> <p>Review of the TB meeting minutes from January 10, 2014, to April 2, 2014, revealed that the TB conducts its meeting to provide oversight on two (2) territorial hospitals at the same time. There was no indication that the TB was apprised of medical errors and quality of care issues, and/or aware what actions, if any, were taken by the hospital to ensure the reduction of medical errors. This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014. Evidence includes the following:</p> <ol style="list-style-type: none"> 1. The hospital's Governing Body failed to take actions related to medical errors. Please refer to A-0286. 2. The hospital's Governing Body failed to assume responsibility for quality improvement and patient safety. Please refer to A-0309. 	A 263			

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A 263	Continued From page 37 3. The hospital's Governing Body failed to demonstrate accountability for adequate resources to improve and sustain the hospital's performance. Please refer to A-0315.	A 263			
A 286	482.21(a), (c)(2), (e)(3) PATIENT SAFETY (a) Standard: Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors. (2) The hospital must measure, analyze, and track ...adverse patient events ... (c) Program Activities (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. (e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: ... (3) That clear expectations for safety are established. This STANDARD is not met as evidenced by: Review of hospital documents revealed that there is no mechanism in place to track medical errors and adverse events, and no preventative	A 286			

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A 286	<p>Continued From page 38</p> <p>measures implemented to reduce medical errors. This failure poses a high potential of harm to patients admitted to this hospital. The governing body was not apprised of medical errors and adverse events, and/or any actions being taken to reduce these medical errors and adverse events. This was confirmed during the interview with the Chairman of the Territorial Board (TB) at her St. Croix office on August 1, 2014. The TB had assumed the functions of the hospital's governing body since the St. Croix District Board had been inactive due to lack of quorum as required by the Virgin Islands' statute.</p> <p>Medical errors and adverse events that resulted in patient harm include:</p> <p>On July 28, 2014, an elderly patient was noted during rounds to have a large hematoma on her forehead. The patient stated that she had fallen out of bed. Nursing staff was unaware of the event at the time of the incident. The physician assistant (PA) did not order any close neurological monitoring and nursing staff did not provide any clinical interventions or investigate the possible consequences of the fall especially while on medications such as Heparin (an anticoagulant), aspirin and Ativan. No post fall interventions were taken until the patient's condition deteriorated. In addition, nursing failed to pursue or inform the medical staff of the reported "dizziness" and "headache" subsequently reported by the patient.</p> <p>On July 30, 2014, at approximately 7:00 p.m, the patient became unresponsive, and a Code Green (respiratory resuscitation needed) was called. An emergency CT scan was ordered that</p>	A 286			

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A 286	<p>Continued From page 39</p> <p>revealed a large subdural hematoma. The patient was intubated and later transferred to the intensive care unit and was given less than a 2% chance of survival.</p> <p>According to an interview with SP #11, it was revealed that the patient said she hit her head on something. SP #11 indicated that she did not see a reason for a repeat CT scan as one had been done upon admission that revealed sinusitis.</p> <p>On June 17, 2014, Patient #3 presented to the emergency department and diagnosed with right pleural effusion. The x-ray showed "an almost complete opacification of the right hemothorax." The physician inserted a chest tube on the left side of the chest inspite of the patient telling the physician that the procedure was being done on the wrong side of the chest.</p> <p>On June 4, 2014, a newborn, Patient #9 was delivered by emergent vacuum delivery due to signs of fetal distress. The baby sustained a subgleal bleed, a known potential complication of vacuum birth delivery. The newborn died.</p> <p>On May 19, 2014, a Patient #27 previously diagnosed with left frontal meningioma arrived in the emergency department and required intubation. During intubation, two (2) front teeth were dislodged and was transferred off island for treatment.</p> <p>On May 10, 2014, Patient #26 presented to the emergency department due to seizure and was admitted to the hospital for treatment. The patient had a fall from his bed on May 11, 2014, and sustained laceration on the eyebrow.</p>	A 286			

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A 286	<p>Continued From page 40</p> <p>On April 27, 2014, Patient #25 presented to the emergency department at 1:34 p.m. with complaints of insidious onset of left chest pain and epigastric pain while lying down. The patient was discharged at 8:10 p.m., April 27, 2014. The patient was brought back to the hospital by ambulance, in full code 72-hours later, April 29, 2014 at 10:51 a.m. and died.</p> <p>On April 10, 2014, a newborn infant. Patient #6 was born via caesarian section. The baby was admitted to Neonatal Intensive Care Unit due to hypoglycemia and an intravenous infusion was started. The patient experienced an intravenous infiltrate with the antibiotic drug, Gentamycin, which resulted in vascular compromise of the finger tips and forearm. The baby was transferred to an off island hospital to the care of a pediatric vascular surgeon.</p> <p>On April 3, 2014, a Patient #8 presented to the emergency department and was diagnosed with cholelithiasis and cholecystitis. She was admitted for laparoscopic cholecystectomy and sustained a bile duct injury and was transferred to an off island hospital for further care.</p> <p>Additional medical errors and adverse events that resulted in patient harm in 2013 include:</p> <p>February 2013, a patient with multiple presentations to the emergency department was given medications that the patient was allergic to. The patient had informed staff and staff dully documented the allergy in the patient's medical record. Nevertheless, the patient received the medication she was allergic to.</p> <p>March 2013, a patient was admitted to the</p>	A 286			

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A 286	<p>Continued From page 41</p> <p>hospital due to right upper quadrant abdominal pain. An endoscopic retrograde cholangiopancreatogram (ERCP) was attempted and failed which resulted in bile duct injury and bile leak. The patient was transferred to an off island hospital for care.</p> <p>April 2013, a patient with abdominal pain presented to the emergency department and was admitted on the third visit. An abdominal exploratory laparoscopy was performed and showed perforated gangrenous appendix with multiple abdominal abscess.</p> <p>April 2013, a patient had an abdominal exploratory laparoscopy and sustained a ruptured bladder.</p> <p>September 2013, patient was admitted due to abdominal pain and was diagnosed with acute cholecystitis. The history and physical examination pre-operatively was incomplete and failed to assess the comorbidities of the patient which include cardiac valve disease, diabetes and hypertension. Immediately post-operatively, the patient desaturated and became unresponsive. The patient was subsequently found to have critical aortic stenosis.</p> <p>October 2013, a patient was admitted to the hospital due to intractable abdominal pain and exploratory laparoscopy was performed. Patient was discharged home but returned to the emergency department and diagnosed with peritonitis. An exploratory laparoscopy was performed and found small bowel contents in the abdomen with a small perforation. The patient died of overwhelming sepsis.</p>	A 286			

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A 286	Continued From page 42 Also, in October 2013, there was a case with a delay in physician presentation to the Emergency Department for a patient diagnosed with ruptured ectopic (tubal) pregnancy. And again in October 2013, there was a case where the operating room staff were not fully prepared to perform in a procedure the hospital had never conducted before, the surgical team lacked cross training, the team experienced multiple equipment failures and found equipment to be missing which resulted with the surgical case taking eight (8) hours.	A 286			
A 309	482.21(e)(1), (e)(2), (e)(5) QAPI EXECUTIVE RESPONSIBILITIES The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: 1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained . (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated. (5) That the determination of the number of distinct improvement projects is conducted annually. This STANDARD is not met as evidenced by:	A 309			

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A 309	<p>Continued From page 43</p> <p>Based upon document review and interview, the hospital's Governing Body failed to demonstrate accountability to ensure patient safety and quality improvement in the provision of care. Evidence includes the following:</p> <p>The statute of the Virgin Islands provides that the authority to supervise the day-to-day operations of the hospital is delegated from the Territorial Board (TB) to the St. Croix District Board (SCDB) for as long as the district board exists. See 19 V.I.C. §242(b) and 244(k). The SCDB is comprised of nine members. Five members shall constitute a quorum. See 19 V.I.C. §243(g). However, due to insufficient numbers of SCDB members, it is inactive. Therefore, the TB had assumed the Governing Body functions for the hospital.</p> <p>Review of the TB meeting minutes from January 10, 2014, to April 2, 2014, revealed that there were no quality assessment and performance reports discussed during the meetings. Consequently, the TB was unable to evaluate quality assessment and performance activities to ensure the reduction of medical errors, patient safety, services provided to patients meet nationally accepted standards of care. This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014.</p> <p>The Governing Body failed to ensure patient safety and the quality of care provided to patients in that numerous cases that lead to patient harm were not brought to the attention of the Governing Body. Therefore, the Governing Body was unable to act upon these issues to ensure the quality of care provided to patients. This practice</p>	A 309			

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A 309	<p>Continued From page 44</p> <p>poses a high potential for harm to patients admitted to this hospital.</p> <p>Medical errors and adverse events that resulted in patient harm include:</p> <p>On July 28th, 2014, an elderly patient suffered an unwitnessed fall. The patient was on medication, Heparin, which is an anticoagulant which is used to prevent the formation of blood clots. Risks for those individuals on an anticoagulant includes the risk of profuse bleeding. The hospital failed to monitor the patient with the known risk of bleeding in accordance with nationally accepted standardds of care. The patient later complained of dizziness and a headache for which she received acetaminophen. No clinical interventions were taken post fall until the patient's condition deteriorated. The patient had a respiratory emergency, was intubated and transferred to the intensive care unit where medical staff indicated that the chance of survival was less than 2% . The patient sustained a subdural hematoma resulting from the fall as revealed by the emergency CT scan.</p> <p>On June 17, 2014, patient presented to the emergency department and diagnosed with right pleural effusion. The x-ray showed "an almost complete opacification of the right hemothorax." The physician inserted a chest tube on the left side of the chest inspite of the patient telling the physician that the procedure was being done on the wrong side of the chest.</p> <p>On June 4, 2014, a newborn, was delivered by emergent vacuum delivery due to signs of fetal distress. The baby sustained a subgleal bleed, a known potential complication of vacuum birth</p>	A 309			

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A 309	<p>Continued From page 45 delivery. The newborn died.</p> <p>On May 19, 2014, a patient previously diagnosed with left frontal meningioma arrived in the emergency department and required intubation. During intubation, two (2) front teeth were dislodged.</p> <p>On May 10, 2014, patient presented to the emergency department due to seizure and was admitted to the hospital for treatment. The patient had a fall from his bed on May 11, 2014, and sustained laceration on the eyebrow.</p> <p>On April 27, 2014, patient presented to the emergency department at 1:34 p.m. with complaints of insidious onset of left chest pain and epigastric pain while lying down. The patient was discharged at 8:10 PM, April 27, 2014. The patient was brought back to the hospital by ambulance, in full code 72-hours later, April 29, 2014 at 10:51 a.m.</p> <p>On April 14, 2014, it was reported to CMS that hospital staff discarded the 22 week fetal remains either in the laundry or the rubbish.</p> <p>On April 10, 2014, a newborn infant was born via caesarian section. The baby was admitted to Neonatal Intensive Care Unit due to hypoglycemia and an intravenous infusion was started. The patient experienced an intravenous infiltrate with the antibiotic drug, Gentamycin, which resulted in vascular compromise of the finger tips. The baby was transferred to an off island hospital to the care of a pediatric vascular surgeon.</p>	A 309		

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A 309	<p>Continued From page 46</p> <p>On April 3, 2014, a patient presented to the emergency department and was diagnosed with cholelithiasis and cholecystitis. She was admitted for laparoscopic cholecystectomy and sustained a bile duct injury. She was transferred to an off island hospital for further care.</p> <p>Additional quality of care issues that resulted in patient harm that occurred in 2013 include:</p> <p>February 2013, a patient with multiple presentations to the emergency department was given medications that the patient was allergic to. The patient had informed staff and staff dully documented the allergies in the patient's medical record yet the patient still received the medication with the known allergic reaction.</p> <p>March 2013, a patient was admitted to the hospital due to right upper quadrant abdominal pain. An endoscopic retrograde cholangiopancreatogram was attempted and failed which resulted in bile duct injury and bile leak. The patient was transferred to an off island hospital for care.</p> <p>April 2013, a patient with abdominal pain presented to the emergency department and was admitted on the third visit. An abdominal exploratory laparoscopy was performed and showed perforated gangrenous appendix with multiple abdominal abscess.</p> <p>April 2013, a patient had an abdominal exploratory laparoscopy and sustained a ruptured bladder.</p> <p>September 2013, patent was admitted due to abdominal pain and was diagnosed with acute</p>	A 309			

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A 309	<p>Continued From page 47</p> <p>cholecystitis. The history and physical examination pre-operatively was incomplete and failed to assess the comorbidities of the patient which include cardiac valve disease, diabetes and hypertension. Immediately post-operatively, the patient desaturated and became unresponsive. The patient was subsequently found to have critical aortic stenosis.</p> <p>October 2013, a patient was admitted to the hospital due to intractable abdominal pain and exploratory laparoscopy was performed. Patient was discharged home but returned to the emergency department and diagnosed with peritonitis. An exploratory laparoscopy was performed and found small bowel contents in the abdomen with a small perforation. The patient died of overwhelming sepsis.</p> <p>Also, in October 2013, there was a case where there was a delay in the physician arriving to the Emergency Department where the patient was diagnosed with ruptured ectopic (tubal) pregnancy and another case where the operating room staff were not fully prepared to perform a procedure that had not ever been done at the hospital before. The surgical team lacked cross training, they experienced multiple equipment failures and equipment was missing which resulted with the surgical case taking eight (8) hours.</p> <p>Telephone interview with the Chairman of the Medical Staff Quality Committee (MSQC) on August 1, 2014, at 11:30 a.m., revealed that cases which results in patient harm are reviewed by the committee. Upon completion of review, it was sent to the Medical Executive Committee</p>	A 309		

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A 309	Continued From page 48 (MEC) for action. There was no communication back to the MSQC from the MEC regarding disposition of cases. Interview with the Chairman of the MEC on August 1, 2014, at 1:40 a.m. revealed that when cases are received from the MSQC, the committee decides what action to take with the case. The Chairman was asked what was done with the case where a patient sustained two (2) dislodge teeth. The Chairman informed the surveyor that the case was reviewed and closed because the hospital offered financial payment for the repair of the dislodged teeth. The Chairman was asked whether quality of care issues are brought up to the attention of the Governing Body. The Chairman stated that no quality of care issues are brought up to the attention of the Governing Body. Please refer to A-049	A 309			
A 315	482.21(e)(4) PROVIDING ADEQUATE RESOURCES [The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:] (4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients. This STANDARD is not met as evidenced by: Based upon documents review and interview, the hospital failed to achieve and sustain compliance	A 315			

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A 315	<p>Continued From page 49</p> <p>by not having adequate resources to improve and sustain the hospital's performance.</p> <p>In December 4, 2013, an updated list of vendors on credit hold was requested that listed ten (10) vendors who were owed more than \$1,750,000.00. In May 2014, the money owed to the vendors on the updated list was \$1,753,881.72.</p> <p>The list included medical supplies such as VI Hospital and Medical Supply which were owed more than \$400,000.00; surgical supplies such as Alcon (intraocular lenses) \$92, 800.00 and Premier, the external consultants required through the Systems Improvement Agreement who is owed more than \$600,000.00.</p> <p>In accordance with the signed Systems Improvement Agreement of November 2011, the hospital was required to choose external consultants to work as independent consultative experts in assisting the hospital to achieve compliance with all applicable regulatory requirements. The first contractor chosen according to the Systems Improvement Agreement, left the hospital in 2012 due to the hospitals failure to pay timely.</p> <p>The hospital then chose another group of consultants. The contract was approved in January 2013, and was to continue through the end of August 2014. Later in January 2013, the hospital notified the external consultants of the need to began decreasing the onsite consulting time to two (2) days a week due to financial difficulties.</p> <p>With the ongoing financial constraints and failed</p>	A 315			

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A 315	Continued From page 50 attempts at contractual financial negotiations, the external consultants later significantly further reduced their days of service onsite as well as the number of consultants. On May 16, 2014, the hospital received a notice of intent to terminate services due to the contractual issues with payment. The hospital failed to have the necessary resources to meet the requirements set forth in the Systems Improvement Agreement by working with independent consultative experts to help the hospital achieve and sustain compliance with all applicable Federal requirements. These findings had been confirmed with the hospital interim CEO and external consultants.	A 315			
A 338	482.22 MEDICAL STAFF The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. This CONDITION is not met as evidenced by: Based on review of hospital documents and interviews, this hospital failed to have an organized and effective medical staff to ensure the quality of medical care provided to patients and all members are properly credentialed in a manner that reflects the member's current competency. The statute of the Virgin Islands provides that the authority to supervise the day-to-day operations of the hospital is delegated from the Territorial Board (TB) to the St. Croix District Board (SCDB)	A 338			

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A 338	Continued From page 51 for as long as the district board exists. See 19 V.I.C. §242(b) and 244(k). The SCDB is comprised of nine members. Five members shall constitute a quorum. See 19 V.I.C. §243(g). However, due to insufficient numbers of SCDB members, it is inactive. Therefore, the TB had assumed the Governing Body functions for the hospital. Review of credential files and interviews, revealed that: 1. Locum tenens physicians were not granted privileges to practice at this hospital by the governing body Please refer to. A-0341 2. The Governing Body was not informed of quality of care issues and adverse events that resulted to patient harm. Please refer to A-0347. 3. Physicians were not credentialed and privileged in a manner that reflected the individual physician's current competency. Please refer to A-0363)	A 338			
A 341	482.22(a)(2) MEDICAL STAFF CREDENTIALING The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates. This STANDARD is not met as evidenced by: Review of the hospital Medical Staff Bylaws revealed on Section 10 that "temporary privileges may be granted by the CEO acting on behalf of the board, upon written concurrence of the chairperson of the service in which privileges will be exercised, or by the President of the Medical	A 341			

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A 341	Continued From page 52 Staff "	A 341			
A 347	Review of six (6) credential files, SP #30, SP #34, SP #35, SP #36, SP #37, and SP #38, revealed that the privileges of these physicians to practice at this hospital were awarded by the Chief Executive Officer (Interim), Chief Medical Officer (Interim), and the Chief of Service. These appointments were not brought up to the governing body for approval before these physicians started practicing at the hospital. 482.22(b) MEDICAL STAFF ORGANIZATION & ACCOUNTABILITY The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: (i) An individual doctor of medicine or osteopathy. (ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located. (iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.	A 347			

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A 347	<p>Continued From page 53</p> <p>This STANDARD is not met as evidenced by: The medical staff failed to ensure the quality of care provided to patients in that numerous cases that lead to patient harm were not brought to the attention of the Governing Body. Consequently, the Governing Body was unable to act upon these issues to ensure the quality of care provided to patients. This was confirmed during the interview with the Chairman of the TB at her St. Croix office on August 1, 2014. This practice poses a high potential for harm to patients admitted to this hospital.</p> <p>Quality of care issues that resulted in patient harm include:</p> <p>Sometime during the evening/night of July 27, 2014, an elderly patient alleged to have an unwitnessed fall as stated to the nurse and physician during morning rounds on July 28, 2014. Noted on the forehead was a hematoma about 3 cm (centimeters) in length. Medical staff did not order any neurological monitoring and there is no evidence of any additional post fall monitoring to assess potential complications with the medications the patient was receiving including Heparin, aspirin and Ativan. No clinical interventions were taken until the patient became unresponsive several days later. A rapid response team was called, the patient intubated and an emergency CT scan was done. The patient sustained a subdural hematoma resulting from the fall. The patient was transferred to the intensive care unit, and the physician documented that the patient had less than 2% chance of survival.</p> <p>On June 17, 2014, Patient #3 presented to the emergency department and diagnosed with right</p>	A 347			

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A 347	<p>Continued From page 54</p> <p>pleural effusion. The x-ray showed "an almost complete opacification of the right hemothorax." The physician inserted a chest tube on the left side of the chest inspite of the patient telling the physician that the procedure was being done on the wrong side of the chest.</p> <p>On June 4, 2014, a newborn, Patient #9, was delivered by emergent vacuum delivery due to signs of fetal distress. The baby sustained subgleal bleed, a known potential complication of vacuum birth delivery. The newborn died.</p> <p>On May 19, 2014, Patient #27 previously diagnosed with left frontal meningioma, arrived in the emergency department and required intubation. During intubation, two (2) front teeth were dislodged.</p> <p>On May 10, 2014, Patient #26 presented to the emergency department due to seizure and was admitted to the hospital for treatment. The patient had a fall from his bed on May 11, 2014, and sustained laceration on the eyebrow.</p> <p>On April 27, 2014, Patient #25 presented to the emergency department at 1:34 p.m. with complaints of insidious onset of left chest pain and epigastric pain while lying down. The patient was discharged at 8:10 p.m., April 27, 2014. The patient was brought back to the hospital by ambulance, in full code 72-hours later, April 29, 2014 at 10:51 a.m.</p> <p>It was reported to CMS on April 14, 2014, that the remains of a 22 week old fetus had been tossed out either in the rubbish or laundry.</p> <p>On April 10, 2014, a newborn infant, Patient #6,</p>	A 347			

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A 347	<p>Continued From page 55</p> <p>was born via caesarian section. The baby was admitted to Neonatal Intensive Care Unit due to hypoglycemia and an intravenous infusion was started. The patient experienced an intravenous infiltrate with the antibiotic drug, Gentamycin, which resulted in vascular compromise of the forearm and finger tips. The baby was transferred to an off island hospital to the care of a pediatric vascular surgeon.</p> <p>On April 3, 2014, a patient presented to the emergency department and was diagnosed with coelithiasis and cholecystitis. She was admitted for laparoscopic cholecystectomy and sustained a bile duct injury. Patient #8 was transferred to an off island hospital for further care.</p> <p>Additional quality of care issues that resulted in patient harm that occurred in 2013 include:</p> <p>February 2013, a patient with multiple presentations to the emergency department was given medications that the patient was allergic to. The patient informed staff and dully documented in the patient ' s medical records.</p> <p>March 2013, a patient was admitted to the hospital due to right upper quadrant abdominal pain. An endoscopic retrograde cholangiopancreatogram was attempted and failed which resulted in bile duct injury and bile leak. The patient was transferred to an off island hospital for caree.</p> <p>April 2013, a patient with abdominal pain presented to the emergency department; was admitted on the third visit. An abdominal exploratory laparoscopy was performed and showed perforated gangrenous appendix with</p>	A 347			

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A 347	<p>Continued From page 56 multiple abdominal abscess.</p> <p>April 2013, a patient had an abdominal exploratory laparoscopy and sustained a ruptured bladder.</p> <p>September 2013, patent was admitted due to abdominal pain and was diagnosed with acute cholecystitis. The history and physical examination pre-operatively was incomplete and failed to assess the comorbidities of the patient which include cardiac valve disease, diabetes and hypertension. Immediately post-operatively, the patient desaturated and became unresponsive. The patient was subsequently found to have critical aortic stenosis.</p> <p>October 2013, a patient was admitted to the hospital due to intractable abdominal pain and exploratory laparoscopy was performed. Patient was discharged home but returned to the emergency department and diagnosed with peritonitis. An exploratory laparoscopy was performed and found small bowel contents in the abdomen with a small perforation. The patient died of overwhelming sepsis.</p> <p>Telephone interview with the Chairman of the Medical Staff Quality Committee (MSQC) on August 1, 2014, at 11:30 AM, revealed that cases which results in patient harm are reviewed by the committee. Upon completion of review, it was sent to the Medical Executive Committee (MEC) for action. There was no communication back to the MSQC from the MEC regarding disposition of cases.</p>	A 347			

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A 347	Continued From page 57 Interview with the Chairman of the MEC on August 1, 2014, at 1:40 PM revealed that when cases are received from the MSQC, the committee decides what action to take with the case. The Chairman was asked what was done with the case where a patient sustained two (2) dislodge teeth. The Chairman informed the surveyor that the case was reviewed and closed because the hospital offered financial payment for the repair of the dislodged teeth. The Chairman was asked whether quality of care issues are brought up to the attention of the Governing Body. The Chairman stated that no quality of care issues are brought up to the attention of the Governing Body.	A 347			
A 363	482.22(c)(6) CRITERIA FOR MEDICAL STAFF PRIVILEGING [The bylaws must:] Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4). This STANDARD is not met as evidenced by: Based upon records review, personnel files and interviews, the hospital failed to ensure that privileges were granted in accordance with all	A 363			

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A 363	<p>Continued From page 58</p> <p>appropriate competencies. Evidence includes the following:</p> <p>Review of ten (10) credential files of physicians SP #24, SP #27, SP #34, SP#32, SP #39, SP #36, SP #30, SP #35, SP #42 and SP #38 granted privileges to practice at this hospital revealed that the Governing Body failed to ensure that all practitioners who provide a medical level of care and/or conduct surgical procedures in the hospital were granted only those specific privileges that practitioners have proven competence to do and that the hospital have the requisite support staff, adequate equipments, and supplies for such procedures to be performed at this hospital.</p> <p>Review of the ten (10) credential files revealed that the physicians were granted generic core privileges for a service line, e.g., anesthesiology, urology, surgery. For example, "Management of patients of all ages except as specifically excluded from practice, rendered unconscious or insensible to pain and emotional stress during surgical, obstetrical and certain medical procedures; including preoperative, intraoperative and post-operative evaluation and treatment; the support of life functions and vital organs under stress of anesthetic, surgical and other medical procedures; medical management and consultation, pain management and critical care medicine, direct resuscitation in the care of patients with cardiac or respiratory emergencies, including the need for artificial ventilation, pulmonary care, supervision of patients in post-anesthesia care units and critically ill patients in special care units."</p> <p>It cannot be assumed that a practitioner can</p>	A 363			

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A 363	Continued From page 59 perform every task/activity/privilege listed/specified for the applicable category of practitioner. The individual practitioner's ability to perform each task/activity/privilege must be assessed and not assumed. If the practitioner is not competent to perform one or more tasks/activities/privileges, the list of privileges is modified for that practitioner. None of the core privileges were amended to reflect the physician 's current area of expertise and that the hospital can support. Hospitals must assure that practitioners are competent to perform all granted privileges. This was verified by the Chairman of the Credentialing Committee during the interview on July 29, 2014, at 10:50 a.m. The Chairman informed the surveyor that the core privileges are being revised to reflect specific procedures and skill sets. However, this revised privileging format was not in place at the time of the survey.	A 363			
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based upon medical records review, documents review, observations and interviews, the hospital failed to demonstrate that nursing services were organized to meet the needs of the patients. Evidence includes the following: 1. The hospital failed to ensure that there were sufficient numbers of personnel to meet patient needs. Please refer to A-0392.	A 385			

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A 385	Continued From page 60	A 385			
A 392	<p>2. The hospital failed to ensure that nursing care was evaluated/supervised. Please refer to A-0395.</p> <p>3. The hospital failed to ensure that care plans were accurate, revised and reflective to meet present patient needs. Please refer to A-0396.</p> <p>482.23(b) STAFFING AND DELIVERY OF CARE</p> <p>The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.</p> <p>This STANDARD is not met as evidenced by: Based on an interview and record review, the hospital failed to ensure that there were sufficient numbers of personnel to provide nursing care within the Labor and Delivery Room for Patient #30. The hospital failed to properly identify and humanely dispose of fetal remains.</p> <p>Evidence includes the following:</p> <p>An interview was conducted with SP #6 on Monday, July 28, 2014, at 1435 hours, regarding fetal remains being lost and not properly disposed of by sending them to the laboratory or the morgue. Patient #30 was admitted on April 25, 2014, with ruptured fetal membranes with chorioamnionitis (infection of the membrane surrounding the fetus in utero) and severe bilateral pneumonia. The attending Neonatologist</p>	A 392			

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A 392	<p>Continued From page 61</p> <p>and OB physician provided counseling regarding possible fetal demise post-delivery of the fetus.</p> <p>On April 26, 2014, at 0155 hours, a 22 weeks and three days old fetus was delivered. The fetus was determined to be incompatible with life, with fused eyelids. A vaginal discharge was noted as "purulent and malodorous."</p> <p>SP #6 indicated that "the mother was provided fetal demise care, to include a fetal bath, pictures with infant and father, and additional mementos provided." The mother at that time was offered the option of funeral arrangements but the mother refused stating, "I don't want to deal with that right now." The fetus was then shrouded in a blue wrap, labeled and placed in a separate locked room with a pathology container labeled, "Fetus, Placenta, Cord and Membranes." The shrouded fetus was then placed in a bassinet; covered by a blanket, placed in a locked room, separate from the pathology container."</p> <p>At that time, is was stated "the OB tech assigned to Labor and Delivery unit had been reassigned to another unit to assist because of a staffing shortage on that unit."</p> <p>The OB tech later returned to the unit to clean the instruments from the previous delivery when the morgue attendant arrived. The OB tech gave the morgue attendant a lab container labeled "Fetus, Placenta, Cord and Membranes." The morgue attendant questioned the whereabouts of the fetal remains. OB tech stated, "that is all that was available." The OB tech was unaware of the fetus being shrouded in a blue wrap in the bassinet."</p>	A 392			

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A 392	Continued From page 62 It was further stated that "on April 28, 2014, two days later, the Pathologist called the Labor and Delivery unit notifying them of the missing fetus in the container labeled "Fetus, Placenta, Cord and Membranes." "We started our investigation at that time." During the same interview with SP #6 it was stated, "the hospital's investigation was unable to determine the final disposition of the fetal remains. They were never found. We can only surmise, the remains went to the laundry room or were thrown out with the trash." In addition, it was determined that the pathology specimen was labeled incorrectly. Although there has been a revision to the hospital's Labor and Delivery and Laboratory policy regarding the handling and disposition of fetal remains and consent forms, the system breakdown that contributed to the inaccurate labeling has not been addressed. Additionally, the insufficient staffing patterns on another unit that required the OB tech to be floated and not to remain within his/her assigned area to perform all duties and functions as the OB tech also have not been addressed.	A 392			
A 395	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on observation, interview and document review, the hospital failed to achieve and sustain compliance since 2012 that ensures each patient received appropriate nursing services.	A 395			

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A 395	<p>Continued From page 63</p> <p>Specifically, nursing staff failed to properly identify pressure sores in one patient and failed to properly ensure the safety of urinary catheter equipment prior to use. Evidence includes the following:</p> <p>1. Patient #14 was admitted to the hospital on July 12, 2014, with diagnoses that included impaired kidney functioning. A review of a document used to track complaints and grievances entitled "Patient Advocate Department Daily Activity Log July 2014" lists a complaint from the 78 year old patient's family member. The complainant stated the patient had developed two bed sores in less than a two week stay. SP #12 replied that the patient "does not have bed sores. It is maceration (skin breakdown associated with prolonged contact with fluid) with skin tear."</p> <p>The Unit Manager was interviewed on August 1, 2014, beginning approximately 8:12 a.m. and was asked about pressure ulcer identification. The staffer described four stages of pressure ulcer development and that the facility's use the Braden system for identification. The nurse also stated that denuded or macerated skin in a pressure area is considered a pressure ulcer and that a skin tear on a pressure area is considered a stage II (pressure ulcer.)</p> <p>When asked about the reply to Patient #14's family's concern, the Unit Manager stated it "was more maceration than skin tear." When asked if a patient can have maceration and pressure ulcer, the nurse stated patients can have both. SP #17, who was present and had observed the wound, stated that the skin tear was noted to be between the gluteal folds (buttocks.) When asked if this is an area where pressure ulcers are</p>	A 395			

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A 395	<p>Continued From page 64 developed, the nurse stated "yes."</p> <p>A Care Plan for "Impaired Skin Integrity" was initiated and included an intervention to implement pressure relieving devices and avoid friction and shearing.</p> <p>2. On July 29, 2014, at approximately 11:15 a.m., Patient #12 was observed to receive a urinary catheterization by SP # 19. The nurse was observed to prepare the patient for the procedure but failed to test the catheter balloon prior to insertion. A rupture of the balloon after insertion could result in unnecessary repeat of the procedure and avoidable discomfort to the patient and risk of infection. Following the procedure the nurse was interviewed. The nurse stated "typically, I would test the balloon."</p> <p>The facility failed to ensure patient received appropriate care and services to prevent pressure related wound development and proper urinary catheterization procedures.</p> <p>3. Based upon medical record review and interview, the hospital failed to implement policies according to their post fall huddle protocol. Evidence includes the following:</p> <p>Patient #4 was admitted through the Emergency Department on July 27, 2014. Documented medical history noted a change in mental status, Heparin used for prophylaxis treatment of blood clots. During rounds on July 28, 2014, the physician and nurse observed a hematoma approximately 3 cm (centimeters) across the forehead. The response to how the bruise happened was that she slipped on something when getting out of bed to the commode the night</p>	A 395			

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A 395	<p>Continued From page 65</p> <p>before (July 27, 2014). She further stated she got back into bed and did not tell the nurse. According to the care plan, the patient was on fall risk protocol which included side rails up, bed alarm and commode at the bedside.</p> <p>Interview with SP #12 indicated nursing staff had been questioned, no one heard the alarm and staff could not answer how the event happened on the 27th of July. It was further stated that the nurse on staff the evening of July 27th had been "floated" from the Post Partum Floor.</p> <p>According to the "Post Huddle Kardex Guideline" which is part of the Fall Prevention Policy expectations are as follows:</p> <p>Update the care plan to include all specific fall prevention strategies and gear them to the specific patient</p> <p>Reassess the patient and document the reassessment</p> <p>When notifying the physicians (physician was present during rounds when hematoma was discovered) ask about holding anticoagulants and question the need for a CAT scan for a potential injury</p> <p>The only update to the care plan was an entry that stated "patient stated she fell on the night of 7-27-14" and interventions only state "monitor for presence of risk factors- altered mental health status and fall prevention every shift - protocol fall reduc (reduction)." Nothing was "geared" to specifically address nor revise and update the intervention since a fall had already happened. The care plan also did not include and</p>	A 395			

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A 395	<p>Continued From page 66</p> <p>interventions or strategies to monitor the patient for any potential consequences due to the use of Heparin or Haldol.</p> <p>There were no nurses notes after the 7/28/14 written at 0800 hours when the entry that first noted the hematoma until 7/28/2014, at 1529 hours, more than eight (8) hours after the discovery of the hematoma. The medical providers note was written on 7/28/2014 timed as 1227 hours, which stated, "note bruise, slight improved sodium, no need for acute intervention."</p> <p>Interview with SP #11 stated "didn't see need for a repeat CAT scan."</p> <p>The hospital staff failed to implement their fall prevention post huddle policy after a known head trauma was identified.</p> <p>4. Based upon record review and interview, the hospital failed to follow assessment documentation policies in the Newborn Intensive Care Unit (NICU). Evidence includes the following:</p> <p>Hospital leadership was asked for the full patient record of Patient #9 born at 1308 on June 4, 2014. The newborn was admitted to the NICU dated by nurses note at 1330 hours on where a newborn assessment was completed that included measurements and full assessment as well as vital signs. The infant had been admitted to the NICU due to the medical history of the mother for further work-up, care and management according to the Neonatal Admit note of June 4, 2014, at 1538 hours.</p> <p>Interview with SP #40 on July 30, 2014, at 2:00</p>	A 395			

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A 395	<p>Continued From page 67</p> <p>p.m., stated that in the NICU, documentation follows their policy, and that would be every hour as well as any "touch times" or meds.</p> <p>Review of the "Administrative Policy & Procedures " dated August 2012, under procedures stated "vital signs assessment should include assessment of temperature, pulse, respiration, blood pressure and oxygen saturation (as necessary) ..."</p> <p>Review of the policy "Assessment, Newborn" reference #2004 provided on July 31, 2014, stated "ongoing assessments (vital signs) initially on admission, at 30 minutes, one (1) hours, two (2) hours, four (4) hours and then every shift or every eight (8) hours and as needed."</p> <p>Review of the neonatal flow sheet documentation revealed the following:</p> <p>6/4/14, at 1330 hours, a Neonatal, assessment was completed with full set of vital signs</p> <p>6/4/14, at 1500 hours, a blood glucose level was done with blood pressure only recorded</p> <p>6/4/14, at 1715 hours, only the temperature was recorded</p> <p>Nursing failed to follow their policy for the completion of vital signs for the newborn in the NICU. Ninety (90) minutes after the full set of the vitals were taken, nursing only recorded the blood pressure. No respirations, oxygen level or pulse had been recorded. Nursing then waited more than two (2) hours and only the temperature of the newborn was taken. Nursing did not record</p>	A 395			

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A 395	Continued From page 68 the blood pressure, respirations or oxygen level. At 1845, the newborn was noted to be hypoactive and required immediate intubation which was unsuccessful and the newborn was pronounced dead at 2130 on June 4, 2014.	A 395			
A 396	482.23(b)(4) NURSING CARE PLAN The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan This STANDARD is not met as evidenced by: Based on observation, interview and document review, the hospital failed to ensure Care Plans were complete and current for all patients. Review of policies and corrective actions reveal that the hospital failed to achieve and sustain compliance with care plans for patients since 2012. A review of a sample of care plans revealed incomplete Care Plans, without actionable and measurable interventions designed to resolve assessed concerns. Additionally the care plans were not individualized to meet each patient's needs nor were they consistently revised or updated when indicated. Evidence includes the following: 1. Patient #14 was admitted on July 12, 2014. The clinical record showed the patient to exhibit self-harming behaviors. On July 14, 2014, at 2:30 p.m., the patient was documented to be "restless and confused" and had removed her Intravenous (IV) catheter and was attempting to pull out her urinary catheter when staff intervened. Another	A 396			

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A 396	<p>Continued From page 69</p> <p>staff member observed the resident later that day to attempt to remove her IV again at 3:51 p.m. Again on July 23, 2014, at 8:30 a.m., the patient was noted to have pulled her IV access. The patient's Care Plans were reviewed. No Care Plan to address the patient's safety needs were developed.</p> <p>2. Patient #15 was admitted to the nursery on March 18, 2014. Care Plans were developed to address identified problems/potential problems including:</p> <p>Alterations in temperature, initiated 3/18/14</p> <p>Altered breathing pattern, initiated 3/18/14</p> <p>Potential for retinopathy, initiated 3/18/14</p> <p>Potential for bronchopulmonary dysplasia(a lung problem affecting infants placed on breathing machines,) initiated on 3/18/14</p> <p>Neurologic damage, initiated on 3/18/2014</p> <p>Hypocalcemia (low levels of calcium in the blood,) initiated 3/18/14</p> <p>Altered glucose metabolism (inability for the body to properly use blood sugar,) initiated 3/18/14</p> <p>Nutrition less than body requirements, initiated 3/18/14</p> <p>Altered growth and development, initiated 3/18/14</p> <p>Anxiety, initiated 3/18/14</p> <p>Prematurity, initiated 3/18/14</p>	A 396			

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A 396	<p>Continued From page 70</p> <p>Potential for eye damage, initiated 3/20/14</p> <p>None of the above listed Care Plans included interventions or interventions to address the identified care needs of the patient.</p> <p>3. Patient #16 was admitted on June 10, 2014, with a diagnosis of renal failure. The diabetic patient was receiving dialysis. The patient was admitted from the Virgin Islands Cardiac Center following an attempt to repair the patients IV access for dialysis. Due to a variety of clinical needs, including a need for a permanent dialysis access (arteriovenous fistula), physical therapy and high blood pressure, the patient was not discharged until June 21, 2014. The care plans for the patient include:</p> <p>Fluid volume excess, initiated on 6/10/14</p> <p>Altered renal tissue perfusion, initiated on 6/10/14</p> <p>Hypocalcemia, initiated on 6/10/14</p> <p>Knowledge deficit, initiated on 6/10/14</p> <p>Risk for altered glucose metabolism, initiated on 6/10/14</p> <p>Patient #16's care plans listed above included no interventions designed to address the patient's problems, with the exception of the care plan for altered renal tissue perfusion. This Care Plan included a single intervention; to monitor the patient's indwelling catheter however, the dialysis patient does not have a urinary catheter according to the documentation in the clinical record.</p>	A 396			

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A 396	Continued From page 71 4. Care Plan review for Patient #4 was initiated on 7/27/14. Included is a notation of high risk for injury (falls) with a note that patient stated she "fell on the night of the 27th." No interventions on the care plan were revised. There is nothing that addresses the hematoma noted on the forehead nor any nursing interventions according to a standard of practice after a noted head injury. In addition, the care plan failed to provide any indication as to the need for the use of an antipsychotic medication nor its increase in dosage. Interview with SP #12 on August 1, 2014, revealed staff are trying to have care plans reflective but the system has so many different methods of nursing making entries. It was further stated that it takes far too much of nursing time with the documentation and that removes them (nurses) from patient care.	A 396			
A 431	482.24 MEDICAL RECORD SERVICES The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital. This CONDITION is not met as evidenced by: Based upon observations, record and document reviews and observations, the hospital failed to achieve and sustain compliance that ensured all medical records met Federal Requirements. Evidence includes the following: 1. The hospital failed to maintain a medical record for each inpatient. Please refer to A-0438.	A 431			

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A 431	Continued From page 72	A 431			
A 438	<p>2. The hospital failed to have a process implemented to ensure unauthorized individuals did not have access to confidential medical records. Pleas refer to A-0441.</p> <p>3. The hospital failed to ensure that medical records were accurate, complete, legible and dated. Please refer to A-0450.</p> <p>4. The hospital failed to ensure all verbal orders were signed promptly. Please refer to A-0454.</p> <p>482.24(b) FORM AND RETENTION OF RECORDS</p> <p>The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the hospital failed to have a medical records system that ensures the prompt retrieval of the medical record of any patient treated or evaluated in any location of the hospital for the past five years. Information found only in a patient's paper Medical Record is not always accessible when needed; newborn electronic and paper medical records cannot be easily retrieved due to problems in coding and/or indexing of newborn medical records. Evidence includes the following:</p>	A 438			

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A 438	<p>Continued From page 73</p> <p>Hospital Policy and Procedures, Manual Code: 5018 Accessibility of the Medical Records stated that the Hospital shall have all patient medical records accessible on a 24-hour per day basis. The Procedure indicates that Medical Records are accessible from the Medical Records file clerk Monday through Friday between the hours of 8 a.m. through 5 am. Between 5 p.m. and 7 a.m. and on weekends, the Medical Records Supervisor, who carries a pager, must be called if a medical record is needed.</p> <p>Interview with the Medical Records Supervisor on July 30, 2014, beginning at 2:15 p.m., identified the Hospital as having a "hybrid" medical records system meaning the medical record is in part electronic (EMR) and in part a paper record. The electronic medical record (EMR) can be accessed throughout the Hospital. However, the EMR is incomplete; significant portions of a patient's medical record including patient assessments, and recent physician orders not yet scanned into the computer, are only found in the paper Medical Record. The Medical Records supervisor stated it takes her about 20 minutes for her to get to the Hospital when she is paged. This delay does not meet the requirements that medical records are immediately accessible 24/7.</p> <p>Based upon observation and interview, the hospital failed to have a medical record system that ensured all medical records were accessible. Evidence includes the following:</p> <p>On July 31, 2014, at approximately 3:20 p.m., during an interview with a staff member from Patient Advocacy department, a review of a newborn infant's care plan was requested whose mother was Patient #17. The staff member was</p>	A 438			

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A 438	Continued From page 74 unable to retrieve the discharged patient's Care Plan from the electronic medical record. The staff member called down to the Medical Records department and was heard to request a copy of the infant's Care Plan. The Patient Advocate was told that the care plan could not be retrieved because the infant now has a name and they would have to "wait until the baby came back in" for another visit.	A 438			
A 441	The hospital medical record system did not allow for prompt or easily retrievable medical records. 482.24(b)(3) PROTECTING PATIENT RECORDS The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas. This STANDARD is not met as evidenced by: Based on observation, staff interview and record review, the hospital failed to ensure that unauthorized individuals could not gain access to patient medical records, and that the Hospital maintained the security of patient Medical Records at all times. Evidence includes the following: During interview with the Medical Records Supervisor on July 30, 2014, at 2:15 p.m., SP #26 reported that the Medical Records room was currently undergoing an OSHA required decontamination of mold and dust. Patient	A 441			

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A 441	<p>Continued From page 75</p> <p>medical records are stored in a large room within the Medical Records suite, placed on on a moveable open shelving system, floor to ceiling. Heavy opaque plastic sheeting was hung at the entrance to the room to contain any contaminants from the cleaning process. Several large ladders were in place. There were no workers present in the room. SP #26 said that three workers were in the room from 8 a.m. until 5 p.m. wiping down the open shelving. When questioned regarding maintaining the security of the medical records, SP #26 stated that she and the staff were "spot-checking" them.</p> <p>At 2:25 p.m., three workers were observed seated at a work table eating lunch. The work table had been set up in the midst of the open shelving containing patient medical records. There were no hospital staff present to ensure that the security of the medical records were being maintained.</p> <p>At 2:45 p.m., three workers were up on ladders cleaning the medical records and shelving. Nothing had been put in place to ensure the security of the patient records. At that time, SP #26 was told that she could not leave the three young men in the medical records library unsupervised, and that the security of the medical records must be maintained at all times.</p> <p>At 3:15 p.m., SP #26 was discussing the situation with the Chief Financial Officer (CFO). According to the Medical Records Supervisor's job description, the CFO was SP #26' s immediate supervisor, and provides direction to the medical records supervisor. On interview, the CFO stated that he was unaware of the need to restrict access to the medical records. He stated that the</p>	A 441			

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A 441	Continued From page 76 hospital had used this vendor for years for various jobs, and that they were "the only game in town" .	A 441			
A 450	The above information was reported to SP#31 who communicated the situation to the Interim CEO. Appropriate security was implemented by requiring medical records staff provide continuous supervision of the workmen. 482.24(c)(1) MEDICAL RECORD SERVICES All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. This STANDARD is not met as evidenced by: Based upon record reviews and interviews, the hospital failed to create medical records that contained legible and complete information with signed/dated or timed medical entries. The hospital failed to achieve and sustain compliance with their medical records since 2012. The hospital was informed again in 2013, that evidence noted numerous medical records that were missing signatures from physicians who wrote orders, nursing staff who provided wound care, failure of nursing to sign for physician orders and standards of practice not being followed with cross outs making notations illegible. Evidence includes but is not limited to the following:	A 450			

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A 450	<p>Continued From page 77</p> <p>A review of the medical record for Patient #3 noted illegible entries and cross outs. The handwritten physicians order form dated 6/18/2014, contained an illegible entry written in the section that indicates the diagnosis. It had been written over and therefore it was unclear as to which side the pleural effusion was on, either right or left. This is significant as the patient would later have a chest tube inserted on the wrong side of the chest cavity even though the patient indicated to the physician who was conducting the procedure that it was the wrong side.</p> <p>Review of the Emergency Physician Record, not dated, also had cross outs as to the time the patient was seen in the Emergency Department. On the top of the form, a handwritten entry placed an "asterisk" next to the letter L (left) then an arrow with the letter R (right) after" chest tube placement without any clarification as to what the notation meant. In the section for the clinical impression, the physician wrote over the laterality of the pleural effusion that made it unclear to read.</p> <p>After a root cause analysis was done due to the error, findings included that the documentation was not consistent nor accurate, the medical record had changes made to it after the error had been discovered, documentation included inappropriate terminology as with the use of a question mark and timing and dating of orders was not appropriately recorded. Included in the investigation is at the time of the error the physician stated the Emergency Department that night was "hectic and short staffed."</p> <p>Review of the Emergency Physician Record for</p>	A 450			

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A 450	<p>Continued From page 78</p> <p>Patient #5 revealed a hand written entry of "expired at" that is left blank. Further in the record, the Emergency Department notes that the Code (emergency resuscitation) was called at 0010 hours and Cardiac Pulmonary Resuscitation began. The time of death was recorded at 0032 hours on April 7, 2014.</p> <p>The cardiovascular assessment documented by the Respiratory Therapist recorded the Code Blue as 0225 hours not as 0010 hours. The Emergency Physician Record has no time recorded for the physician receiving the patient. The SBAR form (situation, background, assessment and recommendations has no clinical signatures nor a time.</p> <p>Review of the medical record for Patient #1 found dates to be written over and not clearly able to be read on the Physicians order sheet, the area for the disposition of the patient with date and time were left blank.</p> <p>The cardiopulmonary resuscitation form is incomplete, no clinicians signatures or initials nor signatures of any responding hospital staff to the emergency situation. An entry for "Epi" is recorded on the form but the remaining sections of the resuscitation form are all blank including the critique sheet. On the electrocardiogram strip are numerous recordings inconsistent with medical record documentation.</p> <p>The Respiratory Therapy Department Ventilator Flow sheet was not legible due to multiple cross outs/markings overs the patient information.</p> <p>The death certificate has cross outs not</p>	A 450			

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A 450	<p>Continued From page 79</p> <p>appropriately noted per standards of practice. In addition, the death certificate indicates the immediate cause of death was a cerebral laceration, open skull fracture and automobile accident that the interval between onset and death was 10 minutes. Manner of death is listed as "accident" with a date of injury of 11/15/85. Patient had no documented accident, head laceration or skull fracture in the medical record.</p> <p>Review of the medical record for Patient #4 revealed on the Physician Order Form date July 27, 2014, at 1447 hours, cross outs without the appropriate notation in accordance with standards of practice. Later on the same day, diagnoses written were written over. On July 29, 2014, the date was illegible due to writing over the first entry. On July 30, 2014, the Physicians Order Form was illegible in the area for the diagnoses and an entry made on July 30, 2014, with additional cross outs.</p> <p>The medical record for Patient #9 contained a Neonatal Code Sheet dated June 4, 2014. Neither the provider or recorder signed or dated the data from the resuscitation efforts.</p> <p>Review of the medical record for Patient #28 noted contradictory documentation as well as missing dates/times and cross outs. The surgical care improvement form did not have the date and time recorded by nursing or the physician at the bottom of the approved form. The pre-operative notes has the time of crossed out/over written from the anesthesia department. The labor and delivery note indicated the patient suffered a second degree perineal tear but the</p>	A 450			

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A 450	<p>Continued From page 80 nurses notes indicates a third degree tear.</p> <p>According to a review of committee minutes, emails, interviews and delinquency reports, the hospital failed to ensure medical records were complete.</p> <p>In May 2013, the minutes of the Medical Executive Committee reflected discussions of options surrounding actions to be taken for delinquent records. Actions included delinquent medical record notification letters to physicians.</p> <p>In the June 2013, minutes of the Medical Executive Committee, notes indicated the committee again discussed the issue and that more than 50% of the Medical Staff at that time had delinquent charts. Actions were to include amendments to the Bylaws and draft language regarding penalties.</p> <p>In the August 2013, minutes, a member spoke of Bylaws and fees for incomplete charts. Actions included notification letters reminding physicians to complete their charts.</p> <p>By email on October 26, 2013, the Chief Medical Officer had notified all medical staff members that audits showed ongoing failure to maintain medical records and that all chart must be completed by October 30, 2013.</p> <p>During the November 2013, meeting, discussion again was held that noted the external consultants were concerned with continued delinquent and incomplete medical records. Also addressed in the minutes was the need for penalties as suspension was not feasible.</p>	A 450			

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A 450	<p>Continued From page 81</p> <p>Interview with SP#26, the Medical Records Supervisor, on July 30, 2014, at 2 p.m., reported the passage of Administrative Policy and Procedure #4014: Monitoring Delinquent/Incomplete Medical Records, which outlines a procedure for notifying practitioners of delinquencies in the completion of medical records with progressive disciplinary measures including suspension of admitting privileges and /or fines when delinquent/incomplete medical records remain. The effective date of this policy is April 2, 2014. SP#26 indicated that this policy was reviewed and approved by the Medical Staff and signed by the Governing Body in April, 2014.</p> <p>Since April 2014, the Medical Records department generates a weekly report of physicians and the number of incomplete medical records and the length of time by which they are delinquent to the President of the Medical Staff. Each practitioner receives a notice of their incomplete medical record, and , according to the policy, should receive a notice of the impending sanctions should the delinquency remain. However, follow-up interview with SP #26 on July 31, 2014, at 2:05 p.m., found that the notices of delinquent medical records to physicians do not include the notice of pending or actual sanctions since the Chief Medical Officer has not yet informed the Medical Staff of these penalties.</p> <p>A review of the most recent report of medical record delinquencies dated July 29, 2014, found 83% (n=58) of all physicians (N=68) had 1 or more medical records that were over 59 days delinquent; of the 58 physicians with delinquencies, 25 of the 58 physicians with delinquent records (43%) had one delinquent</p>	A 450			

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A 450	Continued From page 82 medical record; 6 physicians or 8% of all physicians had 10 or more delinquent medical records with one physician with 67 incomplete records. Although the issue was well known and discussed repeatedly, the hospital has been unable to fully implement their policies to ensure record entries are accurate, timely and complete as well as effectively addressing delinquent medical records.	A 450			
A 454	482.24(c)(1) CONTENT OF RECORD: ORDERS DATED & SIGNED All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations. This STANDARD is not met as evidenced by: Based on document review, the hospital failed to ensure the physician's orders in the clinical records contained signatures of the prescribing physician. Evidence includes the following: 1. A review of the clinical record for Patient #18 was conducted on July 29, 2014, at 9:50 a.m. The record revealed two unsigned telephone orders. A telephone order for a continuation of a foley catheter, dated July 27, 2014, at 11:00 p.m., was found to not have been signed by the physician. Verification of a urinary catheter order, ensures the physician has decided that the benefits of continuing the intervention outweigh	A 454			

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A 454	Continued From page 83 the risks. 2. A telephone order for Clonidine (a medication to lower blood pressure) dated July 3, 2014, for Patient # 19 was noted to not have been signed by the ordering physician. A policy entitled "Telephone, Verbal and Written Orders for Medications" with a revision date of October 2012 instructs that "The prescribing practitioner must counter sign (with date and time) the written record of the verbal/telephone order within 24 hours of giving the order. The facility failed to ensure the clinical records contained validation of telephone orders evidenced by the prescribing physician's order within 24 hours of issuing the telephone orders.	A 454			
A 491	482.25(a) PHARMACY ADMINISTRATION The pharmacy or drug storage area must be administered in accordance with accepted professional principles. This STANDARD is not met as evidenced by: Based on interview, record review and observation the hospital's pharmacy administration failed to have adequately developed a policy for the preparation and utilization of medications needing preparation including multi-dose. Evidence includes the following: Observations on the Dialysis Unit on July 31, 2014, at 11:25 a.m., revealed Heparin in a multi-dose vial being drawn up and prepared for injection at the bedside of Patient #24. The Director of Pharmacy, interviewed on July 30,	A 491			

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A 491	<p>Continued From page 84</p> <p>2014, at approximately 8:15 a.m., stated that the expectation is that all medications are prepared for patient use in either the pharmacy, unit medication room or other designated area. The director said that nurses are informed of this expectation during their orientation process. Educational materials given the nurses during orientation do not address areas appropriate for the preparation of medications.</p> <p>The Director stated this information is orally presented to nurses during orientation. Asked if any other documentation regarding approved areas for medication preparation, the director produced a Pharmacy department Infection Control policy (MM.PD-6) which stated under the Medication Handling heading, "All prescription compounding other than intravenous admixtures, irrigating solutions and hyperalimentation solutions, shall be in the designated compounding area only." This policy further states "all remaining medications that have been in the room of a patient shall be destroyed. "</p> <p>The director also produced the facility's Multi-Dose Vials (MDV's) policy (MM.USP-10), which did not address areas approved for preparation.</p> <p>Another document the director produced was the Medication Administration Auditing Tool which was developed by the Nursing dept. in conjunction with the Pharmacy dept. One of the criteria of this auditing tool is that injectable medications are "prepared in a designated area." The director acknowledged that there is no policy which defines a designated area for the preparation of medications.</p>	A 491			

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A 505 A 505	Continued From page 85 482.25(b)(3) UNUSABLE DRUGS NOT USED Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. This STANDARD is not met as evidenced by: Based on observation and interview, the hospital failed to employ safe medication storage practices to avoid medication errors. Evidence includes the following: 1. On July 30, 2014, beginning approximately 8:30 a.m., inspection of the medication storage areas on the Surgical unit was conducted, accompanied by a SP # 22. Observation of the Omnicel medication distribution system was noted to have mislabeled medication trays. Medications stored for use and labeling of the medication trays were inconsistent to show what medications were stored in the trays. This storage practice places patients at risk for medication errors. The nurse could not explain why the medication tray labels were inconsistent with the medications in the trays. Examples include: Label on tray was Albumen 50 cc vial but tray contained Cipro. Label on tray was Maalox but tray contained Lovoflocin Label in tray was Magnesium Citrate but tray contained Zantac oral solution Label on tray was drug on Unreadable handwritten ____xaparin but tray contained	A 505 A 505			

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A 505	<p>Continued From page 86</p> <p>Gentamycin IV</p> <p>Label on tray was Albuterol but tray contained Albumen 50 cc vial</p> <p>Label on tray was NAACL 10cc but tray contained Silvadene cream</p> <p>Label on tray was 50% Dextrose but the tray contained Magnesium Sulfate</p> <p>Label on tray was Cipro IV but the tray contained Levofloxacin IV</p> <p>Label on tray was NAACL neb but the tray contained Sodium Bicarb 8.4% vials</p> <p>Two trays were not labeled and one contained Potassium Chloride Injectable solution</p> <p>2. Based on observation, interview and record review, the Hospital failed to insure that injectable medication drawn from multi-dose vials are removed from use when medication from a multi-dose vial (MDV) is drawn at the patient's bedside.</p> <p>Patient #24 was admitted to the hospital in June 2014 with severe vascular disease and chronic renal disease. While in the hospital, the patient received hemodialysis three times per week in the hospital's acute end-stage hemodialysis center.</p> <p>On July 31, 2014, Patient #24 was transferred to the Acute Dialysis unit for hemodialysis. According to the medical record and confirmed by SP #33, Patient #24 received 2000 units of Heparin (an anticoagulant injectable medication)</p>	A 505			

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A 505	Continued From page 87 at the start of the treatment at 9:10 a.m. A second dose of 1000 units of Heparin was ordered for mid treatment. At 11:25 a.m., the nurse prepared the second dose of Heparin for administration. SP #33 entered the Medication Storage area and removed a sealed MDV of Heparin from the Omnicell medication distribution unit. Since the MDV was sealed, the nurse labeled the vial with the 28 day expiration date. The nurse then took the MDV of Heparin to the patient station and proceeded to draw the Heparin from the MDV at the patient's bedside. When questioned, the nurse indicated that she always prepared MDV injections at the patient bedside. Following administration of the medication, the nurse was about to return the MDV to the Medication Room when stopped by the surveyor. The nurse was unaware that injectable medications drawn from a MDV must be prepared in the medication room and not brought to the bedside to prevent potential contamination. Returning the MDV to for use for other patients increases the risk for infection. Please refer to A-0491	A 505			
A 545	482.26(c) PERSONNEL Personnel This STANDARD is not met as evidenced by: Based on record review and interview the hospital failed to assure adequate radiological technician staffing to prevent errors. Evidence includes the following: A report made to CMS by the hospital in May 2014, which detailed an incident where the wrong patient was brought from the ER	A 545			

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A 545	Continued From page 88 (Emergency Room) to the Radiology Dept. and subjected to an unnecessary X-Ray procedure. The Director of Radiology Confirmed this incident and supplied the following details during an interview on July 31, 2014, at approximately 10:00 a.m. When the patient was brought into the radiology dept., the radiological technician did not follow the procedure for patient identification. The procedure calls for the technician to ask the patient for the patient's name and then confirm the name by checking the patient's wristband identifier prior to performing any procedure. In this case the technician stated the assumed patients name and interpreted the patient's response as affirmative. The technician did not check the patient's wristband for confirmation. A root cause analysis determined that a significant factor in this event was staffing as the technician was working a 16 hour shift and was fatigued. The technician had worked the double 16 hour shift to cover for another technician who had called out sick. The Director stated the current staffing levels of seven (7) radiological technicians certified for x-ray procedures make it difficult provide coverage and that ideal staffing would consist of 12 radiological technicians with x-ray certification.	A 545			
A 620	482.28(a)(1) DIRECTOR OF DIETARY SERVICES The hospital must have a full-time employee who- (i) Serves as director of the food and dietetic services;	A 620			

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A 620	<p>Continued From page 89</p> <p>(ii) Is responsible for daily management of the dietary services; and</p> <p>(iii) Is qualified by experience or training.</p> <p>This STANDARD is not met as evidenced by: Based on observations, interviews and document reviews, it was determined that the Hospital failed to insure that the food and dietetic service organization of the hospital was met by failing to provide a functional dishwasher to sanitize dishes and equipment. The Hospital also failed to ensure that an emergency food supply was on hand in case of an unforeseen disaster.</p> <p>Evidence includes the following:</p> <p>1. During the inspection of the food services department on July 28, 2014, at 10:30 a.m., the dishwashing machine was not operational. On interview, the Food Service Director reported that the dish machine was out of service, stating that the machine would repeatedly break down due to its age.</p> <p>A Food Safety Inspection report dated 3/2/2014, noted that the dishwasher temperature and sanitizer logs were incomplete, and that the dishwasher water pump seal needed replacement. A report from the external consultants for May/June 2014, noted that the dishwashing machine was not functioning and that a contingency plan was in place using plastic ware, and that the Hospital was considering leasing or purchasing a new dishwasher.</p> <p>During the interview on July 28, 2014, the Food Service Director stated that she has requested a new dishwasher machine in the budget. On July</p>	A 620			

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A 620	<p>Continued From page 90</p> <p>31, 2014, she reported that there has been a dishwasher machine part on order as an interim measure, but most recently, when one part was replaced, another failed. In the interim, hospital meals were served to patients in foam containers which, she admitted, makes it difficult to maintain optimal food temperature.</p> <p>The Food Service Manager reported that ongoing monitoring of food temperatures is part of their QAPI plan. The external consultants report found that the QAPI results for four consecutive months including June 2014, identified ongoing issues with food temperature control.</p> <p>2. During the food service inspection on July 28, 2014, a request was made to see the hospital's emergency food supply to be used in the event of an unplanned, unforeseen disaster. The Food Service Manager stated that no emergency food supply was stocked and available in the hospital. She explained the emergency process in place during hurricane season which included the submission of an emergency food list to specific local vendors 72 hours prior to a potential hurricane.</p> <p>Review of the Department's Emergency Preparedness Plan dated 6/1998, and reviewed 4/25/2014, included a plan for a 2 week supply of food and supplies to feed 400 people. A table had been developed titled "Critical Resource List for a Field Kitchen" which included a list of food and supplies, quantity for each item, its cost and the vendor or supplier. Also included in this plan was an Emergency Month of Menus. However, the plan failed to include how and where additional food could be readily available on hand in case of</p>	A 620			

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A 620	Continued From page 91 an unforeseen and sudden disastrous situation. Observation and assessment of the available food supply, and confirmed on interview with the Food Service Supervisor, the hospital did not have a supply of food available in the case of an imminent, unforeseen emergency or disaster that may last for a period of several days in the event that vendors are unable or unwilling to make a delivery.	A 620			
A 653	482.30(a) APPLICABILITY Standard: Applicability. The provisions of this section apply except in either of the following circumstances: (1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital. (2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter. This STANDARD is not met as evidenced by: Based on interview and document review, the facility failed to maintain the agreement with the Quality Improvement Organization (QIO) as	A 653			

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A 653	<p>Continued From page 92</p> <p>evidenced by the facility's failure to surrender the hospitals readmission rates. Evidence includes the following:</p> <p>On June 24, 2014, CMS spoke with individuals from the QIO at their request. During the conversation it was reported that the hospital had stopped cooperating with the QIO and had not been submitting data to them for the past several months. The QIO had noted and reported at this time that the hospital readmission rates were increasing.</p> <p>On July 29, 2014, approximately 2:00 p.m., an interview was held with the SP #20 regarding case management and discharge planning. The staff member stated that the hospital had maintained collaboration with the QIO but provided no supporting documentation. When asked about the reporting of readmission rates and other relevant data to the Quality Improvement Organization (QIO), the Director of Case Management stated that the QIO representative comes to the facility to retrieve the data every Friday however, the staff member was unable to provide any supporting documentation such as receipts to support this assertion.</p> <p>On July 28, 2014, an interview was conducted with SP #8. It was stated that Utilization Review committee meetings include discussion of discharge planning and that the facility holds "Bed Board" meetings twice daily to discuss patient and hospital unit needs but also stated that the discharge planning representatives' attendance has been "inconsistent.</p> <p>The facility failed to support a system designed to ensure discharge planning efforts were effective</p>	A 653			

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A 653	Continued From page 93 and evidenced by a decline in readmission rates, evaluated by the independent source (QIO.) Please refer to A0806	A 653			
A 724	482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by: 1. Based on observation, interview and document review, the facility failed to ensure maintenance of the ice machines to avoid ingestion of contaminated ice or beverages. Evidence includes the following: On July 29, 2014, observations of the physical environment of the Virgin Islands Cardiac Center (VICC) were conducted at approximately 3:35 p.m. accompanied by the Unit Manager SP #21. The Unit Manager stated that the interior of the ice machine was cleaned by maintenance and that the maintenance sticker was reportedly inside the machine. The date of maintenance was not visible. A request for the policy and procedure for cleaning and the maintenance log were requested. No maintenance log was provided as of the survey exit on August 1, 2014. A Policy and Procedure entitled "Ice storage; water pump cleaning; refrigerator cleaning" dated 8/2011 does not address the process for cleaning the interior of the ice machines to avoid water based infections or to ensure no biological contamination of the ice machine.	A 724			

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A 724	Continued From page 94 2. Based on document and plan review as well as the facility survey walkthrough revealed that the facility failed to maintain the HVAC systems in accordance with NFPA guidelines. The evidence includes: Observation during the facility survey walk through revealed that the second floor 90 minute rated double fire doors separating the Main building from the VICC were unable to automatically close and latch due the extreme air pressure differential between the two buildings. The VICC was observed operating at an extreme negative air pressure which impairs multiple components within the structure including but not limited to: Temperature Humidity, Automatic closure of fire doors Structural degradation due to moisture accumulations inside ceilings and walls Degradation of electrical components Surgical suite environment A review of the VICC construction and As-Built documents and air balancing reports showed that the HVAC air distribution should not be under a negative pressure during normal operation. The facility maintenance representative confirmed the finding throughout the duration of the facility survey.	A 724			
A 747	482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections	A 747			

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A 747	<p>Continued From page 95 and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by: Based on interview, record review and observation the hospital failed to have the Infection Control policies and procedures approved through the Governing Body. Evidence includes the following:</p> <p>During an interview with the Infection Control Practitioner regarding the Infection Control policies and procedures on Wednesday, July 30, 2014, at 1:35 p.m., SP #41 was asked, when the infection control policies were approved by the Governing Body. The response was that, the "the policies and procedures have not been approved by the District Board, however the staff was operating under the new policy and procedures." However, the St. Croix District Board has been inactive due to insufficient numbers of members as required by the Virgin Islands statute. The Governing Body function for the hospital has been taken over by the Territorial Board.</p> <p>During an interview with SP #8 on Thursday, July 31, 2014, at 2:15 p.m. regarding the hospital's Infection Control policies and procedures, she stated, "the facility is using approved Infection Control policy and procedures," contradicting a previous statement made by the ICP.</p> <p>During review of a document provided through SP #5 on Thursday, July 31, 2014, at 1:30 p.m.,</p>	A 747			

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A 747	<p>Continued From page 96 titled "Approved as of 7/31/14" (handwritten in ink, print style) referring to approved policies and procedures in the hospital.</p> <p>The list included:</p> <ul style="list-style-type: none"> - Infection Control Updates for High Level Disinfection & Storage of Patient Control - Infection Control Updates for Safe use of Ultrasound Gel - Infection Control Updates for Transmission Based Precautions - Infection Control Policy & Procedures <p>Review of a document provided through the hospital's 'Command Post' staff on Friday, August 1, 2014, at 2: 00 p.m., titled "Policies Approved by District Board, St Croix, USVI."</p> <ul style="list-style-type: none"> - Safe use of Ultrasound Gel (Infection Control) Policy and Procedure - High level Disinfection (Infection Control) Policy and Procedure - Infection Control Policy & Procedure Manuel - Transmission-based Precautions (Infection Control) Policy and Procedure <p>The CEO of the hospital approved the above policies and procedures on June 4, 2014. The Infection Control Policies and Procedure Manual</p>	A 747			

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A 747	Continued From page 97 were submitted to the Territorial Board on June 23, 2014, and the remaining three Policy and Procedures were submitted on July 16, 2014. The Territorial Board however did not approve any policies and procedures because of canceled meetings.	A 747			
A 806	482.43(b)(1), (3), (4) DISCHARGE PLANNING NEEDS ASSESSMENT (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician. (3) - The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services. (4) - The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital. This STANDARD is not met as evidenced by: Based on observation, interview and document review, the hospital failed to operationalize a systematic, ongoing discharge planning program sufficient to ensure all patients in need of post hospitalization care and services received coordinated discharge planning. Evidence includes the following:	A 806			

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A 806	<p>Continued From page 98</p> <p>On July 28, 2014, a tour of the medical and surgical inpatient units began approximately 10:50 a.m., accompanied by the SP #12 and SP #7. Patient #11, a 62 year old patient, recovering from a partial amputation of the left leg, was observed to be lying in bed.</p> <p>The patient expressed frustration due to being unaware of what was taking place to prepare for discharge. The patient stated that his needs were verbalized but that no response to his concerns have been provided.</p> <p>On August 1, 2014, at 9:37 a.m., the patient was again observed to be isolated in his room. The patient stated there have been no discussions with him regarding planning of his care or discharge planning. The patient stated he was not provided with assistance for discharge planning and that he had asked several times about equipment needed for his return home. The patient stated among other things that he needed a wheelchair and home care. A review of the patient's clinical records shows no Discharge Care Plan to have been developed. The new amputee stated he lives alone and will need "equipment" to care for himself.</p> <p>On August 1, 2014, at approximately 09:25 a.m., Patient #13, a 78 year old patient with kidney failure was observed in bed, accompanied by a close family member. When asked if the patient or family were invited to participate in Care Plan development, both stated "no." The family member stated being present when discharge planning staff came to see the patient but that the Social Worker only asked how many steps were in the patient's home. The family member stated</p>	A 806			

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A 806	<p>Continued From page 99</p> <p>there has been no discussion regarding discharge planning or encouragement to participate in decision-making. A review of the patient's clinical record reveals no Discharge Care Plan to have been developed or discussed with the patient or family.</p> <p>On July 28, 2014, an interview was conducted with SP #8. SP #8 stated that Utilization Review committee meetings include discussion of discharge planning and that the hospital holds "Bed Board" meetings twice daily to discuss patient and hospital unit needs but also stated that the discharge planning representatives attendance has been inconsistent.</p> <p>On July 29, 2014, at approximately 2:00 p.m., an interview was held with the Director of Case Management, SP #20, regarding case management and discharge planning. The staff person stated that the identification of patient needs result from a "trigger" of certain indicators during patient's initial nursing assessment. The staff also stated that her department makes weekly rounds and they review patient records. When asked if they read every patient record, the staffer stated "pretty much." When asked about development of discharge Care Plans and integration of services to ensure all patient needs are addressed, the staff person stated "We collaborate by rounds and meetings. We don't keep a log, we keep the referrals by month."</p> <p>The staff member was then asked what system does the facility use to track what the patients needs are and 1) what interventions have been done to meet those needs and 2) what interventions are still needed to ensure post discharge needs will be addressed. The staff</p>	A 806			

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A 806	Continued From page 100 member showed the surveyor a blank calendar. When the query was clarified and the staff person was asked to show an example of current patient monitoring, the staff person admitted to not having an example, stating "once the patient is discharged, I discard them. When asked about development of discharge Care Plans, the staff person stated "we don't have the integration part, we have to read each other's notes." The facility's Policy and Procedure entitled "Discharge Planning" with a review date of March 21, 2014, instructs that the facility will work with the patient or individuals significant to the patient. The document also states "case management professionals will oversee the development and implementation of the discharge plan ..." The document further explains that the facility will "partner with the Quality Improvement Organization (QIO) to ensure smooth transitions of care." The facility did not provide evidence of a system to track interventions needed to ensure all patient's post hospital care needs were addressed prior to discharge. Neither patients nor their families in need of post hospital care and/or services were consistently included in the discharge planning process.	A 806			
A 811	482.43(b)(6) DOCUMENTATION OF EVALUATIONS The hospital ... must discuss the results of the evaluation with the patient or individual acting on his or her behalf. This STANDARD is not met as evidenced by:	A 811			

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A 811	Continued From page 101 Based on interview and document review, the facility failed to discuss the results of post discharge needs assessments with patients or family members. Evidence includes the following: Patient #11 and Patient #13 state during interviews they were not included in the discussions regarding plans and decisions surrounding their discharge plans and post discharge needs. Please refer to A-0806.	A 811			
A 884	482.45 ORGAN, TISSUE, EYE PROCUREMENT Organ, Tissue and Eye Procurement This CONDITION is not met as evidenced by: Based upon document review and interview the hospital failed to provide evidence of a signed agreement with at least 1 eye bank. Evidence includes the following: The hospital was asked on July 28, 2014, at 11:00 a.m., for the signed agreement the hospital had with an Organ Procurement Organization (OPO). The document produced was an agreement that failed to incorporate an agreement with at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes. Lifelink Organ and Tissue Procurement by signed contract dated June 9, 2014, is the OPO for the donor hospital, Governor Juan Luis Hospital. (GJLH) Interview with SP #5 on July 28, 2014, at 12:30 p.m., and SP #6 revealed there was no	A 884			

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A 884	Continued From page 102 agreement with an eye bank and the hospital had nothing else on file. The failure to have an agreement with an eye bank has the potential to affect all potential eye donors to ensure they were aware of the option to donate usable eyes and the option to decline.	A 884			
A 951	482.51(b) OPERATING ROOM POLICIES Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. This STANDARD is not met as evidenced by: Based on observations, interviews and document review, the hospital failed to ensure safety measures included accounting for surgical supplies used during a surgical procedure additionally, the facility failed to ensure proper skin disinfection techniques were practiced during pre-operative preparation. On July 30, 2014, at approximately 9:35 a.m., an observation of an internal defibrillator (an implanted device designed to support heart functioning) replacement was observed. During the preparation for the surgical procedure, accompanied by the surgeon and the Unit Manager, a staff member was noted to secure the patients beard under a beard guard (a cap, such as is used to cover hair.) During the scrubbing of the surgical site with germicidal sponge, the staff member was noted to wipe using outward circular motion. The sponge was noted to come into contact with the beard guard, sufficient that the beard guard was	A 951			

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A 951	<p>Continued From page 103</p> <p>observed to move upon contact twice. The staff member did not obtain a new sponge and re-scrub the area to ensure no contamination of the surgical site occurred.</p> <p>At the completion of the procedure, the staff did not conduct a count of the surgical instruments or sponges used during the procedure. The instrument tray was observed to be removed from the area and reportedly taken to central sterilization unit.</p> <p>The Association of peri-Operative Registered Nurses (AORN) identifies retained surgical instruments to be a sentinel event (an unexpected occurrence resulting in negative outcome to a patient.) The nationally accepted standard set forth by the AORN stated that conducting an accurate count of instruments used before and after surgery is a critical step to ensure no instruments remain inside patients after the surgery is completed.</p> <p>An interview with the SP #21 was conducted on July 31, 2014, at approximately 3:45 p.m., regarding the observations of the infection control breach with the surgical site preparation and the lack of counts after the procedure. The Unit Manager stated an expectation that the sponges would have been counted after the procedure.</p> <p>Subsequently, the Manager provided a copy of the Policy and Procedures for review. During a followup interview on August 1, 2014, at approximately 10:45 a.m., the Manager referenced the instructions in the Policy and Procedure entitled "Accountability for sponges sharps and instruments" with a review date of March 2014. The document stated that "Sharps</p>	A 951			

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A 951	Continued From page 104 and other items shall be counted on all procedures." The staffer stated that the staff counted instruments and sponges before the procedure. The Unit Manager stated that there was no need for a sponge count (afterward) since the procedure did not involve a large body cavity however when asked if a needle count was done, the staffer stated "They said they did." When the Manager was asked if she saw one conducted, the staffer stated "No, I didn't." When asked about the rationale for counting instruments before a procedure and not after the procedure for comparison, the staffer said the count was to ensure enough supplies were available. A review of the facility's Policy and Procedure entitled "Skin Prepping" with a revision date of 12/08 instructs that the "area will be prepped beginning at the point of incision, wiping the skin in a circular motion outward to the edges of the operative site and repeated two (2) times. The length of the prep will be five (5) minutes." Observation of the pre-operation preparation for the patient during the July 30, 2014, procedure was not consistent with the instructions in the facility's Policy and Procedures. The facility failed to ensure safety measures were consistently employed to avoid inadvertent retention of surgical items and failed to ensure proper surgical site cleansing was done to avoid infection.	A 951			
A1000	482.52 ANESTHESIA SERVICES If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is	A1000			

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A1000	<p>Continued From page 105</p> <p>responsible for all anesthesia administered in the hospital.</p> <p>This CONDITION is not met as evidenced by: Based upon observation, interviews and record review, the hospital failed to ensure anesthesia services were staffed appropriately. Evidence includes the following:</p> <p>During an observation on Monday, July 28, 2014, at 9:30 a.m., the Chief of Anesthesia SP #27 was observed providing general anesthesia in Operating Room #1 for a Bilateral Breast Augmentation on Patient #20. The Anesthesia Record for this case indicated anesthesia was provided by SP #27, with a start time of 0821 hours with an ending time of 1420 hours.</p> <p>The Chief of Anesthesia, while occupied providing general endo-tracheal anesthesia, also served as the Supervising Anesthesiologist for one Certified Registered Nurse Anesthetist (CRNA), SP #28. The CRNA provided General Anesthesia on the same day to Patient #21 during a Laparoscopic Sigmoidectomy in Operating Room #4; this case ran concurrently with the Supervising Anesthesiologist's SP #27 case. SP #28 CRNA's Anesthesia Record indicates the Laparoscopic Sigmoidectomy anesthesia start time was 0935 hours with an ending time of 1130 hours.</p> <p>During an observation on Wednesday, July 30, 2014, at 9:00 a.m., SP #27 was observed providing general anesthesia in Operating Room #4 during a Fractional Dilation & Curettage on Patient #22.</p> <p>The Anesthesia Record for this case indicated anesthesia was provided by SP #27, with a start</p>	A1000			

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A1000	<p>Continued From page 106</p> <p>time of 0840 hours with an ending time of 0956 hours while also serving as the Supervising Anesthesiologist for one Certified Registered Nurse Anesthetist (CRNA), SP #28. CRNA SP #28 provided monitored anesthesia care on the same day to Patient #23 during a left ocular lens procedure with possible lens change with suture in Operating Room #6; this case ran concurrently with the Supervising Anesthesiologist's SP #27 case.</p> <p>During an interview with the Operating Room Supervisor SP #29 on Wednesday, July 30, 2014, at 10:30 a.m. regarding observations provision, the supervisor stated, "they will sometimes take cases as the supervising Anesthesiologist."</p> <p>During an interview with the Chief of Anesthesia on Thursday, July 31, 2014, at 8:25 a.m., regarding observations regarding the provision of anesthesia services, he stated, "the supervising should not take cases. "</p> <p>During a record review of the "Responsibilities of the Anesthesia Chief Policy" on Thursday, July 31, 2014, at 1:15 p.m., revealed, "The duties of the Anesthesia Chief shall include, but not be limited to the following:</p> <ul style="list-style-type: none"> - Directing the administration of all anesthesia throughout the hospital; planning directing and supervising - Supervising all clinically related activities of the Anesthesia Department - Establishing staff schedules etc ..." <p>The hospital failed to ensure that the individual</p>	A1000			

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A1000	Continued From page 107 responsible for supervising the delivery of anesthesia services by CRNA's would be "immediately available" to provide immediate hands on interventions in the event of any situation requiring assistance.	A1000			
A1100	482.55 EMERGENCY SERVICES The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice. This CONDITION is not met as evidenced by: Based on review of hospital documents and interviews, this hospital failed to achieve and sustain compliance as they failed to ensure that the emergency needs of individuals presenting the Emergency Department are met. Evidence includes the following: 1. The hospital failed to ensure that an individual who was placed on psychiatric observation and on every 15-minute suicide watch was prevented from elopement. During an observation of care provision in the emergency department (ED) on July 30, 2014, at 3:00 p.m., Patient #29 approached the nurses' station asking for his clothes and belongings so that he could leave. Review of the patient's medical record showed that this patient was awaiting transfer to a hospital in St. Thomas, V.I. for inpatient psychiatric treatment. The ED nursing supervisor informed the surveyor that this patient is on "72-hour hold," so the patient cannot leave. Review of the physician's order revealed that the psychiatrist ordered on July 30 2014, at 09:00 a.m., the following: "psychiatric	A1100			

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A1100	Continued From page 108 observation, no family visits, every 15 minutes suicide watch." In spite of the hospital security officer in close proximity to the patient's room and the patient's room was in front of the nurses' station, the patient managed to elope. Hospital security and local police searched the grounds and perimeter for several hours before the patient was found unharmed and returned to the ED.	A1100			
A1112	482.55(b)(2) QUALIFIED EMERGENCY SERVICES PERSONNEL There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility. This STANDARD is not met as evidenced by: Based on documents review and interviews, the hospital failed to ensure that staff are qualified and demonstrated the skills and specialized training required in order to be able to meet the emergency needs of patients presenting to the Emergency Department (ED). Evidence includes the following: Review of the personnel file of SP #10 with the Human Resources on July 31, 2014, revealed that she was hired in December 1990. There was no evidence to show that SP #10 had demonstrated competencies in nursing skills required in the ED. This was confirmed by SP #8	A1112			

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A1112	Continued From page 109 during an interview at her office on August 1, 2014, at 08:24 a.m. SP #8 informed the surveyor that SP #10 had been reassigned from the ED to "Quality" and SP #25 will take over the responsibilities of SP #10 in the ED effective August 1, 2014, but there will be a two (2) months transition period. Review of the personnel file of SP #25 with the Human Resources on July 31, 2014, revealed that there was no evidence to show that SP #25 had demonstrated competencies in nursing skills required in the ED. This was confirmed by SP #8 during an interview at her office on August 1, 2014, at 08:24 a.m. SP #8 stated that although SP #25 will take over the responsibilities of SP #10 in the ED effective August 1, 2014, there will be a two (2) months transition period. SP #8 was asked to provide any documentation from the file that indicated specific training that would pertain to the Emergency Department for SP # 10 or SP #25 but was unable to find any evidence of specific emergency department education and/or training.	A1112			
A1161	482.57(b)(1) RESPIRATORY CARE PERSONNEL POLICIES Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing. This STANDARD is not met as evidenced by: Based upon interview and personnel file review and policy review, the hospital failed to ensure that respiratory personnel were qualified to provide respiratory services in accordance with	A1161			

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A1161	<p>Continued From page 110 hospital policy. Evidence includes the following:</p> <p>One of the responsibilities provided through respiratory services of the hospital includes responding to Code Blue (meaning immediate resuscitation) and trauma alerts. The hospital provides services to adults, pediatrics and newborns.</p> <p>According to the policy of the hospital for respiratory staff, all respiratory therapists are required to maintain certifications in Basic Cardiac Life Support (BCLS), Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS) and Neonatal Resuscitation Program (NRP).</p> <p>BCLS certification qualifies an individual to provide emergency life-saving treatment when someone suffers from a heart related crisis such as stabilization of a persons's airway, breathing and circulation. ACLS certification assures individuals are qualified with systems of care, and immediate post- cardiac arrest care, airway management and related pharmacology. PALS training focuses on management of pediatric respiratory emergencies including pediatric assessments and vascular access. NRP certification qualifies and individual in the resuscitation of the newborn including at the time of delivery.</p> <p>Review of 2 of 4 personal files` SP #1, SP #2, SP #3 and SP #4 revealed outdated certifications. SP #1 PALS was due for renewal February 2013. NRP certification was due for renewal July 2014. SP #3 NRP was due for renewal March 28, 2014.</p> <p>Although SP #1 and SP #3 had taken several</p>	A1161			

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A1161	Continued From page 111 lessons as part of the NRP certificate program, the program is not considered completed until the individual has completed a cognitive evaluation and successfully participated in skills and stimulation review and testing with an NRP instructor. These findings were confirmed with hospital staff.	A1161		