

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001158	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/14/2011
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NAME OF PROVIDER OR SUPPLIER ST VINCENT SURGERY CENTER OF TERRE HAUTE	STREET ADDRESS, CITY, STATE, ZIP CODE 227 E MCCALLISTER DR TERRE HAUTE, IN47802
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility #: 005650</p> <p>Survey Dates: 09-13/14-11</p> <p>Surveyors:</p> <p>Billie Jo Fritch, RN, BSN, MBA Public Health Nurse Surveyor</p> <p>Jennifer Hembree, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 09/26/11</p>	S0000		
S0153	<p>410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on document review and interview, the facility failed to provide documentation of orientation to the facility or applicable facility</p>	S0153	S 153Housekeeping staff has completed an appropriate orientation with signed documentation. Contracted housekeeping service has been	10/10/2011

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

TITLE

(X6) DATE

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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S0230	<p>policies/procedures for 4 of 4 (CS#1 - CS#4) contracted housekeeping staff.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility documents on 9-13-11 and 9-14-11 lacked evidence of facility orientation to the facility or applicable facility policies/procedures for 4 of 4 (CS#1 - CS#4) contracted housekeeping staff. 2. Interview with B#3 on 9-14-11 at 1115 hours confirmed there is no documentation of orientation to the facility or applicable facility policies/procedures for 4 of 4 (CS#1 - CS#4) contracted housekeeping staff. <p>410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based on document review and interview, periodic reviews of the center by the Utilization Review (UR) Committee were conducted by a physician having</p>	S0230	<p>made aware of the need for orientation for all staff who work at the center. Housekeeping staff have been added to our Orientation Checklist for Licensed Independent Practitioner, Allied Health Personnel and Agency. Materials Manager and Clinical Manger are responsible to ensure ongoing compliance through verification of housekeeping staff working at the center.</p> <p>S 230The center has three (3) non-investors who perform utilization review as of July 29, 2009. The investor physicians participated in the review for the</p>	10/10/2011	

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	<p>ownership in the facility.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility Utilization Review Committee documents on 9-13-11 indicated that D#7, a physician with financial ownership in the facility, conducted periodic reviews of facility's services as part of the UR Committee in the first quarter of 2011. 2. Interview with B#4 on 9-14-11 at 1330 hours confirmed D#7 has financial ownership in the facility and conducted reviews for the UR Committee in the first quarter of 2011. 		<p>1st quarter of 2011 in order to familiarize them with the Sims Criteria which was newly implemented. The investors have not participated in the review since the 1st quarter of 2011 and will not participate going forward. The administrator is responsible to ensure compliance through delegation/coordination of review.</p>		

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S0332	<p>410 IAC 15-2.4-2.2(a)(1)</p> <p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following:</p> <p>(1) A process for determining the occurrence of the following reportable events within the center:</p> <p>(A) The following surgical events:</p> <p>(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both</p> <p>(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.</p> <p>(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both</p> <p>(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:</p> <p>(AA) Objects intentionally implanted as part of a planned intervention.</p> <p>(BB) Objects present before surgery that were intentionally retained.</p> <p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as</p>			

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	<p>microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p>			

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	<p>(D) The following care management events:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration. Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug=drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <p>(AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable</p>			

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	<p>because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the center.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or (BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the center.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on the grounds of the center.</p> <p>(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</p> <p>Based on document review and interview, the facility's Quality Assurance and</p>	S0332	S 332All center occurrences are currently reported to QAPI committee who meets quarterly.	10/10/2011	

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	<p>Performance Improvement (QAPI) Committee failed to establish a process to determine the occurrence of events, reportable to the Indiana State Department of Health (ISDH), within the center.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility QAPI documentation on 9-13-11 and 9-14-11 lacked evidence that events reportable to the ISDH were included in the facility QAPI program. 2. Interview with B#4 on 9-14-11 at 1330 hours confirmed the facility QAPI committee does not include events reportable to the ISDH in the facility QAPI program. 		<p>A policy will be developed to address the reporting of of reportable events to the ISDH. An agenda item will be added to the QAPI committee to address the state requirement. The administrator and clinical director are responsible to assure ongoing compliance along with members of the Quality Committee.</p>		

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S0334	<p>410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a) (1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p> <p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event</p>			

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	<p>that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on document review and interview, the facility failed to establish a policy and procedure to identify and report adverse events to the Indiana State Department of</p>	S0334	S 334All center occurrences are reported quarterly to QAPI committee. A policy will be developed to address the reporting of reportable events to	10/10/2011	

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S0400	<p>Health (ISDH).</p> <p>Findings include:</p> <p>1. Review of facility policies and procedures on 9-13-11 and 9-14-11 lacked evidence that the facility had developed a policy/procedure to identify and report adverse events to the ISDH.</p> <p>2. Interview with B#4 on 9-14-11 at 1330 hours confirmed the facility has not developed a policy/procedure to identify and report adverse events to the ISDH.</p> <p>410 IAC 15-2.5-1(a)</p> <p>(a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on observation, the facility failed to provide an environment that minimized risk to patients for 1 of 2 operating rooms (OR #2).</p> <p>Findings include:</p> <p>1. During observation of the operating rooms (OR) beginning at 12:20 p.m. on 9/14/11 and accompanied by staff member #2, the following was observed:</p> <p>(A) The pad on the table in OR #2 was torn in the middle exposing the foam making it impossible to disinfect the table</p>	S0400	<p>ISDH.An agenda item will be added to the QAPI Committee to address the state requirement.The administrator and clinical director are responsible to assure ongoing compliance along with members of the Quality Committee.</p> <p>S 400The table pad has been replaced.The infection control nurse will educate the staff on the importance of checking pads on equipment/furniture along with immediate reporting to repair/replace at an inservice on conducted 10/12/11.The clinical director and infection control nurse are responsible to ensure compliance through observation.</p>	09/19/2011	

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S0404	<p>between patients and prevent fluid waste from going into the foam pad.</p> <p>410 IAC 15-2.5-1(b)</p> <p>(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p> <p>Based on document review and staff interview, the facility failed to maintain an effective infection control program regarding immunization history for 7 of 9 staff members.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Staff members #P1, P2, P4-P6, B3 and B4 personnel files lacked acceptable evidence of immunization history to Varicella. Staff member #B4 indicated in interview at 2:00 p.m. on 9/14/11 that the facility has no policy in place to prevent staff members from working if there was a community outbreak of Varicella. He/she also verified personnel file 	S0404	S 404All center staff have been requested to provide proof of the varicella immunization (9/30/2011). Staff have been requested to provide proof by 10/14/2011. Those staff who have not provided proof will be scheduled on 10/14/2011 for a varicella titre to be drawn by Occupational Health.A policy has been developed to ensure compliance as well this item has been added to the new hire checklist.The administrator and clinical director are responsible.	10/14/2011

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S0444	<p>information for staff members #B3 and B4 contained a self attested questionnaire.</p> <p>3. Staff member #4 verified personnel file information for staff members #P1, P2, and P4-P6 contained a self attested questionnaire.</p> <p>410 IAC 15-2.5-1(f)(2)(E)(ix)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>Based on document review, observation, and interview, the facility failed to ensure staff members adhered to dress code policies for 1 of 1 anesthesia provider and 1 of 1 central sterile tech observed.</p> <p>Findings include:</p> <p>1. Facility policy titled "Attire in Patient</p>	S0444	S 444The dress code policy has been reviewed with the staff at a recent staff meeting (9/30/11) to address the use of cover gowns and cloth hats. Supply and location of cover gowns and disposable caps have been reviewed to ensure adequate supply and correct locations of the supply to ensure ongoing compliance. Administrator, clinical director, IC nurse are responsible	09/30/2011	

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	<p>Care Areas (Restricted, Semi-Restricted, Non-Restricted) last reviewed/revised 8/09 states on page 1, under Proper dressing Attire: "All personnel entering the restricted areas of the surgical suite should be in appropriate O.R. attire:iv. Personal clothing should not be worn in the restricted areas,unless completely covered by scrub suit." and page 2 states under III. b: "If an employee leaves a restricted area and becomes contaminated by leaving the building, the employee must change his/her scrubs, shoe covers, and hat before re-entering restricted areas. c. An employee may, however, wear a lab coat before leaving a restricted areas and entering a public area. i. The employee must remove his/her lab coat before re-entering the restricted area and must change his/her shoe covers and hat."</p> <p>2. During the survey on both 9/13/11 and 9/14/11, staff member #7 (central sterile tech) was observed in and out of the lounge area, in the front business office area, going outside and also in the back restricted area. He/she did not wear a lab coat when leaving the restricted area.</p> <p>3. During survey on both 9/13/11 and 9/14/11, staff member #8 was observed with a cloth skull cap on and was observed going outside the building on</p>		to monitor compliance along with assistance from all staff members through direct observation.		

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S1000	<p>9/13/11 without a lab coat on and returning to the restricted area.</p> <p>4. Staff member #2 indicated during interview at 1:00 p.m. on 9/14/11 that staff member #8 was to wear a disposable bouffant hat over his/her personal skull cap.</p> <p>410 IAC 15-2.5-6</p> <p>The center shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Pharmaceutical services must have the following: Based on observation, the facility failed to remove outdated medications from patient stock for 1 pediatric code box observed.</p> <p>Findings include:</p> <p>1. During observation of the code cart beginning at 1:10 p.m. on 9/14/11, the following was observed in the pediatric code box on the bottom shelf of the code cart: (A) Five (5) 1 ml vials of Epinephrine with an expiration date of 7/11.</p>	S1000	S 1000All outdated medication have been replaced.In a planned infection control in-service (10/12/11), the infection control nurse will reinforce the importance of following the policy requiring the checking of outdated medications.To ensure compliance, the Pharmacist consultant has been made aware of the issue to ensure his monthly checks are complete.The clinical director is responsible to ensure compliance through observation.	10/12/2011

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S1012	<p>410 IAC 15-2.5-6(3)(B)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(B) Drug administration according to established center policies and acceptable standards of practice. Based on document review and staff interview, the facility failed to ensure facility policy titled "CRNA Nurse Anesthetist Duties" was followed for 11 of 20 medical records reviewed (Patients #N1, N4, N8, N10-N13, N15-N17, and N20).</p> <p>Findings include:</p> <p>1. Facility policy titled "CRNA Nurse Anesthetist Duties" last reviewed/ revised 8/25/09 stated under procedures: "10. Requires countersigning by the physician on all orders for medications."</p> <p>2. Patients #N1, N4, N8, N10-N13, N15-N17, and N20 medical records had orders for medications signed by staff member #8 (CRNA) with no physician countersign.</p>	S1012	<p>S 1012The medical staff have been reminded of the requirement for co-signing CRNA orders.To ensure compliance, the order form has been revised to include a physician signature. The medical records coordinator has added this to her checklist for the chart review.Clinical director, business office manager and medical records coordinator are repsonsible to ensure compliance through observation and quarter medical record consultant review.</p>	10/11/2011	

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S1164	<p>3. Staff member #8 indicated in interview at 1:50 p.m. on 9/13/11 that his/her orders for medications and labs are to be cosigned or written by a physician.</p> <p>4. Staff member #2 verified at 2:00 p.m. on 9/14/11 that the CRNA orders for medications were not cosigned by a physician for the above patients.</p> <p>410 IAC 15-2.5-7(b)(4)(B)(i)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, the facility failed to include all patient care equipment on a schedule of preventative maintenance to ensure it's safety for patient care.</p>	S1164	S 1164Stretchers, wheelchairs and nurse call have been checked to ensure that all are in good working order.All above equipment have been added to preventative maintenance schedule/checklist for ongoing	10/10/2011			

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S1198	<p>Findings include:</p> <ol style="list-style-type: none"> Review of facility documents on 9-13-11 and 9-14-11 lacked evidence that preventative maintenance was provided during 2010 or 2011 for the emergency nurse call system, wheelchairs, or patient stretchers. Interview with B#3 on 9-14-11 at 1050 hours confirmed the facility does not provide preventative maintenance service for the emergency nurse call system, wheelchairs, or patient stretchers to ensure they are safe for patient care. <p>410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based on document review and interview, the facility failed to coordinate emergency and disaster preparedness with appropriate community, state, and federal agencies.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of facility documents on 9-13-11 and 9-14-11 lacked evidence that 	S1198	<p>compliance. Safety officer will ensure compliance.</p> <p>S 1198A letter was given to the Hospital in 2010 in order to comply and participate with emergency preparedness and disasters. The center did not receive a written acknowledgement. The safety officer has contacted the area hospital to coordinate service and obtain an acknowledgement letter from the hospital. The safety officer is responsible to ensure compliance on a yearly basis</p>	10/14/2011	

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	<p>the facility had coordinated emergency and disaster preparedness with any community or governmental agency.</p> <p>2. Review of facility documents on 9-14-11 indicates a letter addressed to: To Whom It May Concern: Our center has limited resources available in the event of an emergent situation. We have been instructed by our local area hospitals that they would likely not utilize our services. Because of this factor, the center does NOT participate in local community-wide disaster programs.</p> <p>3. Interview with B#4 on 9-14-11 at 1310 hours confirmed the ASC has not coordinated emergency and disaster preparedness with any community or governmental agencies.</p>		through written communication.		