

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 03/27/2012	
NAME OF PROVIDER OR SUPPLIER TERRE HAUTE HEART CENTER OUTPATIENT CATH LAB				STREET ADDRESS, CITY, STATE, ZIP CODE 455 E HOSPITAL LN TERRE HAUTE, IN 47802			
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility #: 009610</p> <p>Survey Dates: 3-26/27-12</p> <p>Surveyor: Billie Jo Fritch, RN, BSN, MBA Public Health Nurse Surveyor</p> <p>QA: claughlin 03/29/12</p>	S0000					

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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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the facility failed to include the direct service of laboratory and the contracted service of security in the facility Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings included:</p> <p>1. Review of facility documents on 3-26-12 and 3-27-12 lacked evidence that the direct service of laboratory and the contracted service of security were included in the facility QAPI program.</p> <p>2. Interview with B#1 on 3-27-12 at 1140 hours confirmed the direct service of laboratory and the contracted service of security are not included in the facility QAPI program.</p>	S0310	As of 03/29/2012, the services of the laboratory and security have been added to the QAPI program and are being evaluated on a quarterly basis. I will be monitored by the Cath lab Director and reported to the Board of Directors quarterly as part of the QA process.	03/29/2012			

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S0320	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(2)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(2) All functions, including, but not limited to, the following:</p> <p>(A) Discharge and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the facility failed to include medication errors and the response to patient emergencies in the facility's Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings included:</p> <p>1. Review of facility documents on 3-26-12 and 3-27-12 lacked evidence that the facility included medication errors and the response to patient emergencies in the facility's QAPI program.</p> <p>2. Interview with B#1 on 3-27-12 at 1140 hours confirmed the facility failed to include medication errors and the response to patient emergencies in the facility's QAPI program.</p>	S0320	<p>A plan has been written (in P&P) and implemented into the QAPI program to evaluate all functions, including but not limited to; 1) Discharge and tranfer of patients, 2) infection control, 3) medication errors and 4) response to patient emergencies. This will be evaluated and monitored on a quarterly bases by the Director of Cath lab and reported to the Board of Directors. This has been reveiwed with the staff members and the phsycian.</p>	03/29/2012			

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S0332	<p>410 IAC 15-2.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 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: (1) A process for determining the occurrence of the following reportable events within the center: (A) The following surgical events: (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 (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. (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 (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained.</p>			

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	<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 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</p>			

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	<p>the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p> <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.</p> <p>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</p>			

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	<p>progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable 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>			

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	<p>Based on document review and interview, the facility failed to develop a policy/procedure to determine reportable occurrences, those reportable to the Indiana State Department of Health (ISDH), that occur within the center.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Review of facility documents on 3-26-12 and 3-27-12 lacked evidence that the facility had developed a policy/procedure to determine reportable occurrences, those reportable to the ISDH, that occur within the center. 2. Interview with B#1 on 3-27-12 at 1140 hours confirmed the facility had not developed a policy/procedure to determine reportable occurrences, those reportable to the ISDH, that occur within the center. 	S0332	A (P&P) has been written to encompass all sections of tag S 332. It has been reviewed with all staff and physician. This will be monitored in the Quarterly QA by the Director of Cath lab and reported at the Quarterly Board of Directors meetings.	03/29/2012			

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S0334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 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; or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>			

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	<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 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,</p>	S0334	A P&P has been written, has	03/29/2012

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	<p>the facility failed to include reportable occurrences, those reportable to the Indiana State Department of Health, in the facility Quality Assurance and Performance Improvement (QAPI) program.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of facility documents on 3-26-12 and 3-27-12 lacked evidence the facility included reportable occurrences, those reportable to the ISDH, in the facility QAPI program. 2. Interview with B#1 on 3-27-12 at 1140 hours confirmed the facility has not included reportable occurrences, those reportable to the ISDH, in the facility QAPI program. 		<p>been incorporated into the QAPI program regarding the reportable occurrences outlined by the ISDH and reviewed with all staff and physician. The occurrence is to be reported to the director at the time of occurrence. The monitoring and reporting of any event will be the responsibility of the Director of the cath lab. It will be reported to the ISDH and the Board of Directors</p>				

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S0772	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based on document review and interview, the medical staff failed to complete a History and Physical Examination (H & P) within 30 days of the procedure for 2 of 30 (P#8, P#30) patient's medical records reviewed as required by the approved medical staff rules and</p>	S0772	<p>This deficiency was addressed by reviewing the P&P with all staff and physician. This is to be monitored by all nursing staff during the admission of each patient. Any discrepancies will be brought to the attention of the physician prior to the procedure. The patient will not be brought</p>	03/29/2012

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	<p>regulations.</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of medical records on 3-27-12 indicated the following: <ol style="list-style-type: none"> P#8's H & P was completed on 9-16-11; the patient's procedure was completed 10-21-11. P#30 's H & P was completed on 8-23-11; the patient's procedure was completed on 10-24-11. Review of the Medical Staff Rules and Regulations, approved 9-19-11, on 3-26-12 and 3-27-12 indicates the following: A history and physical examination shall be performed on all patients within 30 days of the date of the procedure. Interview with B#1 on 3-27-12 at 1140 hours confirmed the medical staff rules and regulations require the H & P be completed on all patients within 30 days of the date of the procedure; B#1 confirmed the H & P for patients P#8 and P#30 were completed more than 30 days before the procedure and did not follow the approved medical staff rules and regulations. 		<p>into the procedure room until the H&P is done or updated. It will be the physician's responsibility to update the H&P at that time. This will also be monitored by the Director of the Cath lab.</p>				