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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____ | X3) DATE SURVEY COMPLETED 04/19/2016 |
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| 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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| S 0000 Bldg. 00 | This visit was for a State licensure survey. Facility Number: 009610 Dates: 4/18-19/16 QA: cjl 05/27/16 | S 0000 | | |
| S 0153 Bldg. 00 | 410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C) Require that the chief executive officer develop and implement policies and programs for the following: (C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies. Based on document review and interview, the Chief Executive Officer (CEO) failed to implement policies for orientation of 4 contracted employees (P1, P2, P3 and P4). Findings: 1. Review of facility policies lacked documentation of a policy for contracted staff orientation. | S 0153 | Policy is in place and all employees have orientation documentation on file. An orientation checklist has been made and put in the new employee packet. This will be monitored by the Cath Lab Manager for compliance. | 05/05/2016 |

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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| S 0156 Bldg. 00 | <p>2. Review of personnel files for the contracted staff P1, P2, P3 and P4 lacked documentation of facility or job orientation.</p> <p>3. On 4/19/16 at 11:45am, A1, Register Nurse (RN) Office Manger/Administrator, indicated documentation of orientation for contracted staff was not maintained and no policy was in existence.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on document review and interview, the chief executive officer failed to maintain current job descriptions for each employee providing direct patient care for 3 of 3 (P1-P3) personnel files reviewed.</p> | S 0156 | All employees have signed and dated job descriptions on file. This will be reviewed at the date of employee evaluation annually, and will be monitored by the Cath Lab Manager. | 05/05/2016 |

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| | <p>Findings:</p> <ol style="list-style-type: none"> 1. Policy 3.01, Position Descriptions, revised/reapproved 1/13/16 indicated: <ol style="list-style-type: none"> A. completed position descriptions shall be reviewed by the Director of the position and approved by the Executive Director and reviewed with employees in the position. B. position descriptions shall be revised as changes in the job occur. C. all position descriptions shall be reviewed annually to assure that they are current. 2. Review of personnel files confirmed personnel: <ol style="list-style-type: none"> A. P1 (Registered Nurse [RN]) was hired on 11/1/96 and lacked documentation of job description. B. P2 (RN Manager) was hired on 11/29/99 and lacked documentation of job description. C. P3 (Radiology Technician [RT]) was hired on 7/13/01 and lacked documentation of job description. 3. Staff P2 (RN Manager) was interviewed on 4/19/16 at approximately 1100 hours confirmed personnel files reviewed lacked documentation of job descriptions and policy for position descriptions was not followed. | | | |

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| S 0310 Bldg. 00 | <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 center failed to ensure 2 services (biomedical engineering and nursing) were included in their quality assessment and performance improvement (QAPI) evaluations for 2015.</p> <p>Findings:</p> <p>1. Review of the policy and procedure titled Quality Assurance Plan indicated the following:</p> <p>a. The Quality Assurance (QA) Plan of the (Center) provides a comprehensive general framework within which all of the functions and activities related to assuring the quality...can be integrated</p> | S 0310 | Nursing services and Biomedical services have been added to QAPI and monitored by the Cath Lab Manager. This will be reviewed by the Governing Board and QA meeting quarterly as per policy. | 05/05/2016 |

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| S 0400 Bldg. 00 | <p>and evaluated.</p> <p>b. There are certain elements that by their very nature require inclusion in the review activities of the Committee: Nursing Services</p> <p>c. The Plan/Policy was approved 1/13/16.</p> <p>2. Review of Governing Board and QA meeting minutes dated 1/25/15, 4/23/15, 7/16/15 and 10/24/15 lacked documentation of QA review or evaluation of contracted biomedical engineering services and nursing services.</p> <p>3. On 4/19/16 at 12:40pm, A1, Register Nurse (RN) Office Manger/Administrator, indicated the contracted biomedical engineering and nursing services were not included in QA review or evaluation.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 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. Based on document review and interview, the facility failed to provide a safe and healthful environment that</p> | S 0400 | A risk assessment has been completed with the aid of the Vigo County Health department. And the Terre Haute Heart Center is | 05/05/2016 |

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| | <p>minimizes infection exposure and risk to patients, health care workers and visitors by failing to assess the risk of exposure to tuberculosis in the facility annually.</p> <p>Findings:</p> <p>1. Policy 10.06, Tuberculosis Infection Control Program, revised/reviewed 1/13/16 indicated:</p> <p>A. the Executive Director shall assess the risk of exposure to tuberculosis in the facility annually as follows: Contact the County Health Department to determine the community TB profile.</p> <p>B. based on a low incident rate in the community and no infected patient or employee incidents; the facility has been evaluated as a "minimal" risk. In the event of an increase in incidents in the community, patients or employees the risk may change requiring revisions in this program.</p> <p>2. Staff P2 (RN Manager) was interviewed on 4/19/16 at approximately 1100 hours confirmed risk of exposure to tuberculosis in the facility has not been assessed annually as per facility policy and confirmed lack of documentation from the County Health Department verifying the facility has been evaluated as "minimal" risk.</p> | | <p>considered a low to minimal risk for Tuberculosis. This will be assessed on an annual bases. This will be monitored by the Cath Lab Manager and reviewed by the Board of Directors.</p> | | | | |

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| S 0526 Bldg. 00 | <p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.</p> <p>Based on document review and interview, the facility failed to annually assess competency for all nursing and other center personnel performing point of care testing for 3 of 3 (P1-P3) personnel files reviewed.</p> <p>Findings:</p> <p>1. Policy 5.09, Care of Diabetic Patient, revised/reapproved 1/13/16 indicated: A. if the patient is an insulin-dependent diabetic, perform an accucheck to check their blood sugar. B. regardless of how a patient's diabetes is managed whether it be oral or injection, anytime there is suspicion of hypoglycemia, one may perform an accucheck.</p> <p>2. Review of personnel files confirmed personnel: A. P1 (Registered Nurse [RN]) was</p> | S 0526 | Competency testing has been completed and documented and in employees files. This includes sedation and analgesia accucheck machines and point of care. This will be monitored and updated by the Cath Lab Manager annually. | 05/05/2016 |

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| S 0704 Bldg. 00 | <p>hired on 11/1/96 and lacked documentation of annual assessment for competency of point of care testing.</p> <p>B. P2 (RN Manager) was hired on 11/29/99 and lacked documentation of annual assessment for competency of point of care testing.</p> <p>C. P3 (Radiology Technician [RT]) was hired on 7/13/01 and lacked documentation of annual assessment for competency of point of care testing.</p> <p>3. Staff P2 (RN Manager) was interviewed on 4/19/16 at approximately 1100 hours and confirmed personnel files reviewed lacked documentation of annual assessment for competency of point of care testing and confirmed need for staff annual assessment for competency of point of care testing based on policy for care of diabetic patient.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(1)</p> <p>The medical staff shall do the following:</p> <p>(1) Conduct outcome-oriented performance evaluations of its member at least biennially.</p> <p>Based on document review and</p> | S 0704 | A documented outcome- oriented | 05/05/2016 | | | |

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| S 1010 Bldg. 00 | <p>interview, the medical staff (MS) failed to conduct outcome-oriented performance evaluations for 1 of 1 MS members (MD1) within the past 2 years.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of Medical Staff Bylaws and Rules and Regualtions lacked documentation of a policy/rule for performance evaluations of the MS. The Bylaws were approved 4/23/16. 2. Review of MS member MD1's credential file lacked documentation of an outcome oriented performance evaluation within the past 2 years. 3. On 4/19/16 at 10:30am, A1, Register Nurse (RN) Office Manger/Administrator, indicated the MS did not have other staff to conduct outcome oriented performance evaluations of its members and no outside evaluation had been conducted for MD1. <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> | | performance evaluation has been completed on 1 of 1 MD member. and will be completed q 2 years with reappointment for staff privileges. This will be monitored by the Cath Lab Manager and reviewed by the credentialing committee for re-certification. | |

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| | <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on document review, observation and interview, the center failed to ensure proper labeling of 2 open medication vials (midazolam and lidocaine) in 2 areas (surgical suite and nursing station).</p> <p>Findings:</p> <p>1. Review of the policy titled Pharmaceutical Services indicated the following: Labeling: When multidose vials are initially used they shall be dated with the current date and will have an effective expiration date 30 days from the date of initial use or the expiration date. The policy was approved 1/13/16.</p> <p>2. On 2/19/16, during facility tour, the following was observed:</p> <p>a. At 12:40pm, in the surgical suite was an open vial of midazolam 50mg/10ml (no indication of single dose use or multi-dose use) with approximately 5ml solution. The vial lacked indication of when it was opened/accessed or adjusted expiration date.</p> | S 1010 | The policy for open vials of (Multi dose vial medications) has been found in the Pharmacy policy# 8.01. I have added labeling of Multi dose vials to the QA checklist to ensure compliance. It will be monitored quarterly by the Cath Lab Manager and reviewed during the QA meetings. | 05/05/2016 |

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| S 1152 Bldg. 00 | <p>b. At 12:45pm, in the pre/post operative nursing station medication storage area was an open vial of lidocaine HCL (hydrochloride) 1:100,000 50ml MDV (multi-dose vial) with approximately 45ml solution in the vial. The vial lacked indication of when it was opened/accessed or an adjusted expiration date.</p> <p>3. On 2/19/16 at 12:45pm, A1, Register Nurse (RN) Office Manger/Administrator, indicated the facility policy for open vials of medication is that once open, they be marked/labeled with the date opened and/or a new expiration date.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(B)</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>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plan and equipment by qualified personnel as follows:</p> | | | |

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| | <p>(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) 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 center failed to ensure preventive maintenance (PM) was performed on 1 piece of equipment (the back-up generator) according to schedule and manufacturer recommendation from December 2015 to present.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of back-up generator PM logs indicated the last weekly test(s) were performed December 2015. The documents lacked indication of test(s) performed or dates of actual tests. On 4/19/16 at 10:45am, A1, Register Nurse (RN) Office Manger/Administrator, indicated a copy of the generator manual was not available, that up-to-date logs had not been submitted to A1 and therefore could not verify the tests were performed, that the logs did not have dates of testing, nor did they contain information about the tests that were performed. | S 1152 | <p>Logs for back up generator have been turned in and verified completion, New logs have been devised to ensure checks are dated and timed for weekly checks. These will be turned in monthly and reviewed quarterly as part of QA meeting and Monitored by the Cath Lab Manager.</p> | 05/05/2016 |

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| S 1196 Bldg. 00 | <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAc 15-2.5-7(c)(5)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(5) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with center policy and state and local regulations. Based on document review and interview, the center ensure annual fire inspections for the past 2 years (2014 and 2015).</p> <p>Findings:</p> <p>1. Review of facility documents indicated the most recent State or Local fire inspection was done on 3/19/13.</p> <p>2. On 4/18/16 at 3:00pm, A1, Register Nurse (RN) Office Manger/Administrator, indicated 3/19/13 was the most recent fire inspection.</p> | | | S 1196 | <p>The state fire marshal's office has been notified that an inspection needs to be completed and they will send an inspector to the facility on 06/09/2016. I am waiting on the report, however the inspector said he found no violations. The state office sent me a report for the 2015 inspection which I had no record of. This will be monitored by the Cath Lab manager annually.</p> | | 06/03/2016 |