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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>150056 | X2) MULTIPLE CONSTRUCTION<br>A. BUILDING 00<br>B. WING _____ | X3) DATE SURVEY COMPLETED<br><br>01/31/2014 |
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| S000000 | <p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005051</p> <p>Survey Date: 1-27/31-14</p> <p>Surveyors:<br/>Jack I. Cohen, MHA<br/>Medical Surveyor</p> <p>John Lee, RN<br/>Public Health Nurse Surveyor</p> <p>Cleone Peterson<br/>Medical Surveyor</p> <p>Albert Daeger<br/>Medical Surveyor</p> <p>Brian Montgomery, RN<br/>Public Health Nurse Surveyor</p> <p>Linda Plummer, RN<br/>Public Health Nurse Surveyor</p> <p>Saundra Nolfi, RN<br/>Public Health Nurse Surveyor</p> <p>Ken Ziegler<br/>Medical Surveyor</p> | S000000 |  |  |
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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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| S000178   | <p>Steve Poore<br/>Medical Surveyor</p> <p>Linda Dubak, RN<br/>Public Health Nurse Surveyor</p> <p>QA: cloughlin 02/11/14</p> <p>410 IAC 15-1.3-2<br/>POSTING OF LICENSE<br/>410 IAC 15-1.3-2(a)</p> <p>(a)The license shall be conspicuously posted on the hospital premises in an area open to patients and public. A copy shall be conspicuously posted in an area open to patients and public on the premises of each separate hospital building of a multiple hospital building system.</p> <p>Based on observation, the hospital failed to conspicuously post a current hospital license in an area open to patients and the public in the main lobby of Methodist Hospital.</p> <p>Findings:</p> <p>1. On 1-27-14 at 1:10 pm, in the presence of employee #A23, it was observed in the main lobby of Methodist Hospital, a State hospital license was posted with an expiration date of 12-31-12.</p> | S000178   | <p>Tag S 178 Rule 410 IAC 15-1.3-2<br/>Findings: Posting of current hospital license in Methodist lobby. Corrective Action: On January 30, 2014, the current hospital license was posted in the Methodist lobby. Responsible Person: Director of Nursing Operations for Methodist Hospital</p> | 02/03/2014           |   |

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| S000270            | <p>410 IAC 15-1.4-1<br/>GOVERNING BOARD<br/>410 IAC 15-1.4-1(a)(6)</p> <p>(a) The governing board is legally responsible for the conduct of the hospital as an institution. The governing board shall do the following:</p> <p>(6) Review, at least quarterly, reports of management operations, medical staff actions, and quality monitoring, including patient services provided, results attained, recommendations made, actions taken and follow-up.</p> <p>Based on document review and interview, the governing board failed to review quality reports of 8 activities/services.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the governing board minutes for calendar year 2013 indicated they did not include review of quality reports for Methodist/IU Adult/Riley hospitals of the activities/services of air and ground ambulance, biohazardous waste hauler, extracorporeal shock wave lithotripsy, laundry, maintenance, massage therapy, and tissue transplant.</li> <li>2. In interview, on 1-30-14 at 3:15 pm, hospital staff confirmed the above and no further documentation was provided</li> </ol> | S000270       | <p>Tag S 270 Rule 410 IAC 15-1.4-1 Findings: The Governing Board failed to review quality reports of eight activities and services. Corrective Action (s): Quality reports for these areas will be reviewed at the Hospital Quality Council on March 27, 2014 and reported to the Governing Board on April 23rd, 2014. Additionally, the quality indicators for the following services (air and ground transportation; biohazardous waste hauler; extracorporeal shock wave lithotripsy, laundry, maintenance, massage therapy, and tissue transplant) were added to the required list of departmental quality indicators which are reviewed by the Quality Council and ultimately, the Governing Board. Each area was reeducated regarding the importance of completing and</p> | 03/27/2014           |

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| S000278   | <p>prior to exit.</p> <p>410 IAC 15-1.4-1<br/>GOVERNING BOARD<br/>410 IAC 15-1.4-1(b)(2)(A)(B)(C)(D)</p> <p>(b) The governing board is responsible for the conduct of the medical staff. The governing board shall do the following:<br/>(2) Ensure that:<br/>(A) the requests of practitioners, for appointment or reappointment to practice in the hospital, are acted upon, with the advice and recommendation of the medical staff;<br/>(B) reappointments are acted upon at least biennially;<br/>(C) practitioners are granted privileges consistent with their individual training, experience, and other qualifications; and<br/>(D) this process occurs within a reasonable period of time, as specified by the medical staff bylaws.<br/>Based on interview and document review, the governing board failed to</p> | S000278   | <p>submitting the reports to the Quality Department in a timely and standard manner. Each department will complete a quality report and disseminate to appropriate stakeholders for review. Reminders will be emailed on a routine basis to each department. Any identified gaps will be immediately discussed with respective department designee for performance improvement. Responsible Person: Director of Quality or her designee</p> <p>Tag S 278 Rule 410 IAC 15-1 (b)(A)(B)(C)(D)Findings: review of surgery schedule appeared that</p> | 01/31/2014           |   |

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|   | <p>ensure that individuals were granted privileges consistent with their request for privileges by a physician assistant (PA) was performed (staff #4).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. On 01-28-14 at 0925 hours, staff #50 confirmed that staff #4 performs the act of harvesting veins for open heart surgeries.</li> <li>2. Review of staff #4's credential/privileging file lacked documentation that staff #4 requested privileges to perform vein harvesting.</li> <li>3. On 01-29-14 at 1345 hours, staff #55 confirmed that staff #4's credential/privileging file lacked documentation of requesting the privilege to harvest veins.</li> </ol> |   | <p>PA was vein harvesting without evidence of privileges although he was proceeding through the privileging process.</p> <p>Corrective Action: On or before January 31, 2014, Medical Staff Services reviewed Staff #4's file to ensure that he was in the process of being proctored to obtain vein harvesting privileges and was not independently performing the procedure at the time of survey. Staff #4 is in the process of being proctored in order to build his case log to show clinical competency to perform vein harvesting. On March 12, 2014, Staff #4's case log will be presented to the Credentials Committee for review and approval. Then, the case log and request for privileges will be reviewed and approved by the Medical Staff Executive Committee on March 18, 2014 and the Board on March 20, 2014. Responsible Person: Director of Medical Staff Services</p> |                      |   |

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| S000322   | <p>410 IAC 15-1.4-1<br/>GOVERNING BOARD<br/>410 IAC 15-1.4-1(c)(6)(H)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following:<br/>(6) Require that the chief executive officer develops policies and programs for the following:<br/>(H) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based on document review and interview, the facility failed to follow its policy and assure that all departmental and organizational policies and procedures in use were implemented in a uniform manner including evidence of review or revision and approval by a department representative and/or committee of the facility for 5 of 18 policy/procedures provided for review.</p> <p>Findings:</p> <p>1. The policy/procedure Development and Revision of Policies and Procedures (approved 3-12) indicated the following:<br/>" This policy assures that Departmental and Organizational policies and procedures are developed, reviewed, approved, educated and implemented in a consistent manner ...Policies are to be</p> | S000322   | <p>Tag S 322 Rule: 410 IAC 15-1.4-1 (c) (6) (H) Findings: departmental and organizational EVS policies were not implemented, reviewed and revised in a uniform manner consistent with policy. Corrective Action (s): The following EVS policies: ES 1.0 Daily Cleaning Order, ES 2.0 D/C Transfer Cleaning, ES 5.0 Sterile Room Cleaning , ES 14 DOT Proper Waste Handling, and Riley Pest and corresponding procedure documents were sent to appropriate personnel for formatting to comply with ADM 1.01 Development and Revision of Policies and Procedures. On February, 27, 2014, Infection Control Committee provisionally reviewed and approved the EVS policies listed above. On or before March 7, 2014, the Infection Control Committee reviewed</p> | 02/27/2014  |  |   |  |

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|   | <p>signed by department leadership, i.e. directors and medical directors, if applicable. " The Appendix A - New Policy Template attached to the policy/procedure indicated a standardized format for all IU Health policies and procedures.</p> <p>2. The IU Health Environmental Services Department process documents titled Daily Cleaning Order E.S. #1 (revised 9-13), Discharge/Transfer Cleaning E.S. #2 (revised 2-13), Sterile Room Cleaning E.S. #5 (revised 9-13) and DOT Proper Waste Handling E.S. #14 (revised 9-13) failed to indicate they were prepared in accordance with the Appendix A - New Policy Template and lacked documentation of approval by a responsible person.</p> <p>3. The document titled Riley Hospital for Children Pest - Policy, Process &amp; Standards of Service prepared and provided by the environmental services (EVS) department failed to indicate it was prepared in accordance with the Appendix A - New Policy Template and lacked documentation of approval by a responsible person or a date of approval.</p> <p>4. During an interview on 1-30-14 at 1345 hours, the EVS director A16 confirmed that the E.S. #1 and E.S. #2</p> |   | <p>and approved respective policy and procedure documents in accordance with the ADM 1.01 Development and Revision of Policies and Procedures.<br/>Responsible Person (s): Director of Environmental Services</p> |   |  |   |  |

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| S000406            | <p>process documentation was not prepared in the standardized policy format.</p> <p>5. During an interview on 1-30-14 at 1445 hours, the EVS training and quality coordinator A27 indicated that the staff had performed the E.S. #1 and E.S. #2 document revisions dated 9-13 and confirmed that the documentation lacked the name of a responsible person.</p> <p>410 IAC 15-1.4-2<br/>QUALITY ASSESSMENT AND IMPROVEMENT<br/>410 IAC 15-1.4-2(a)(1)</p> <p>(a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. 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.<br/>Based on document review and staff interview, the facility failed to ensure 5 services provided by an off-site were being monitored as part of Indiana University Health comprehensive quality assessment and improvement (QA&amp;I) program: Biohazard Waste, Dietary, Maintenance, Telepsychology, and sleep lab, failed to include monitors and</p> | S000406       | <p>Tag S 406 Rule 410 IAC 15-1.4-2 Findings: Hospital failed to ensure inclusion of all services including services provided by contractors in the comprehensive QAPI program. Corrective Action (s): IU Health Quality leadership met with departments including contractors to ensure that Biohazard Waste Hauler, Dietary, Maintenance, Tele-Psychology, Sleep Lab, Shock Wave</p> | 03/02/2014           |

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|                    | <p>standards for 3 services/activities (biohazardous waste hauler, extracorporeal shock wave lithotripsy, and laundry) and failed to include standards for 1 service/activity (tissue transplant).</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>2013 Indiana University Health Hospital Quality Improvement Plan implements all service with direct or indirect impact on patient care quality shall be reviewed under the quality improvement program.</li> <li>Indiana University Health Saxony Hospital off-site location did not provide documented evidence that Biohazard Waste, Dietary, Maintenance, Telepsychology, and sleep lab were part of Indiana University Health Hospital Quality Improvement Plan.</li> <li>At 10:00 AM on 1/31/2014, staff member #F5 confirmed 5 services provided by Indiana University Health Saxony Hospital off-site location.</li> </ol> |               | <p>Lithotripsy, Laundry, and Tissue Transplant developed performance improvement indicators as part of the organizational QAPI plan by March 2nd, 2014. Each area will report results of their PI monitors at a minimum of twice yearly at the Hospital Quality Council beginning on March 27, 2014. The performance indicators for the services listed above will be the following: Biohazardous Waste Hauler: 1) Audit for observation of Trash Hauler separating or handling trash, after being put into cart, wearing proper PPE. 2) Audit for observation of Trash Hauler changing cart liner. Responsible Person: Director of Environmental Services<br/>Dietary: 1) Team lead rounds daily. 2) Manager rounds weekly for labeling and other issues. 3) Quality monthly tracer for compliance. Responsible Person: Quality, Risk, Compliance Program<br/>Maintenance: 1) Completion of Tier I Preventative Maintenance checks 2) Completion of Tier II Preventative Maintenance checks Responsible Person: Hospital Maintenance Administrator<br/>Tele-psychology: 1) Video machine checks to ensure ready for patient use. Responsible Person: Quality, Risk, Compliance Program<br/>Manager<br/>Sleep Lab: 1) Timeliness of testing scores. 2) Timeliness of</p> |                      |

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|                    | <p>4. Review of the facility's QAPI program for Methodist/IU Adult/Riley hospitals indicated it did not include monitors and standards for the services/activities of biohazardous waste hauler, extracorporeal shock wave lithotripsy, and laundry.</p> <p>5. Review of the facility's QAPI program for Methodist/IU Adult/Riley hospitals indicated it did not include standards for the service/activity of tissue transplant.</p> <p>6. In interview, on 1-30-14 at 3:15 pm, employee #A22 confirmed the above</p> |               | <p>physician interpretation 3) Interscorer reliability Responsible Person: Quality Assurance Coordinator Shock Wave Lithotripsy: 1) Temperature mangement Responsible Person: Urology Service Line Coordinator Laundry: (Measures will be built on a report received from the contracted service.) 1) Hospital related injuries 2) Sharps received from facility 3) Stain percentages 4) Measurement of Sour PH in wash baths for all linens Responsible Person: Vice President of Supply Chain Mangement Tissue Transplant: 1) Audit tissue documentation within Tissue Track System. Responsible Person: Specialty Coordinator for Surgical Services</p> |                      |

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| S000422 | <p>410 IAC 15-1.4-2.2<br/>QUALITY ASSESSMENT AND IMPROVEMENT<br/>410 IAC 15-1.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) improvement program shall be designed by the hospital to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the hospital 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 serious adverse event is determined to have occurred by the hospital'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</p> <p>(D) identify the reportable event, the quarter of occurrence, and the hospital, 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) hospital employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be</p> |  |  |  |
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|                    | <p>identified by a hospital that:</p> <p>(A) receives a patient as a transfer; or</p> <p>(B) admits a patient subsequent to discharge;</p> <p>from another health care facility subject to a reportable event requirement. In the event that a hospital identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying hospital 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 hospital'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 hospital. The department's public report will be issued annually.</p> <p>(e) Any reportable event listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the hospital between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> |               |   |                      |

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|   | <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 15-1.4-2.2)<br/>Based on document review and interview, the facility failed to ensure that potential reportable events were submitted to the Indiana State Department of Health (ISDH).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>The IU Health policy/procedure Sentinel and Adverse Event Management (approved 2-12) failed to indicate a provision for submitting each potentially reportable event brought to the attention of the quality assessment and improvement program to the ISDH per 410 IAC 15-1.4-2.2(a)(2) including a timeframe for submission.</li> <li>During an interview on 1-30-14 at 1425 hours, staff A3 confirmed that the policy/procedure lacked a provision for submitting a potentially reportable event to ISDH.</li> </ol> | S000422   | <p>Tag S 422 Rule 410 IAC 15-1.4-2.2 Findings: policy was missing provision regarding submitting each potential reportable event brought to QAPI to the ISDH per 410 IAC 15-1.4-2.2(a) (2) including a timeframe for submission.<br/>Corrective Action(s): On February 24, 2014, the RM 1.01 Sentinel and Adverse Event Management policy was reviewed and revised to include the provision mentioned above. On February 26, 2014, the departmental policy was reviewed for informational purposes at the Academic Health Center Policy Steering Group meeting. Responsible Person: Director of Risk Managment(Please see attached supporting documentation and language in Appendix D.)</p> | 02/26/2014           |   |

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| S000554   | <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(a)</p> <p>(a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on document review, observation and interview, the facility failed to follow manufacturer's recommendations to provide a safe and healthful environment that minimizes infection exposure and risk to patients in 5 instances (Central Sterile department, Surgery, Biohazardous Waste Storage area, Clean Linen Receiving area, Dirty Linen area).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of the manufacturer's recommendations for the Medisafe Direct Surgical Instrument Cleaning Brushes indicated the following;<br/>"Reusable brushes should be disinfected or sterilized at least daily."</li> <li>2. On 01-28-14 at 1010 hours, staff #69 confirmed that the reusable brushes used to clean dirty surgical instruments and devices are not disinfected.</li> <li>3. On 01-28-14 at 1040 hours during the tour of the Methodist Surgery</li> </ol> | S000554   | <p>Tag S 554 Rule: 410 IAC 15-1.5-2 (a) Findings: MH-biohazardous waste-trash on floor and outside doorway<br/>Corrective Action (s): On or before, January 28, 2014, the trash on floor and outside doorway was removed. Monitoring: Beginning March 2014, these areas will be monitored on an ongoing basis during EVS rounding to ensure the deficiency has been corrected and will not recur. Responsible Person: Director of Environmental Services Findings: Surgical instrument cleaning brushes were not disinfected daily per manufacturers recommendations. Corrective Action (s): On or before January 27, 2014, staff were educated via a Quality Bulletin to consider all brushes disposable, i.e., dispose of all brushes after one use until policy revision consistent with the manufacture's recommendations could be reviewed, approved, and disseminated to respective staff members. Responsible Person: Administrative Director of Sterile Processing Department Findings: Neptune docking station was in</p> | 03/02/2014  |  |   |  |

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|   | <p>Department, a device used to dispose of surgical body fluids, a Neptune, was observed to have the docking station in room A2183, a room for clean equipment.</p> <p>4. On 01-28-14 at 1040 hours, staff #50 confirmed that the Neptune docking station in room A2183 was being used to dispose of surgical body fluids.</p> |   | <p>clean equipment room (A 2183)<br/>Corrective Action (s): On February 26, 2014, the Neptune docking station in the clean equipment room was taken out of service. In the interim other means of disposal are being used until the new Dornoch system in the soiled holding room in Core V (A 2339) has been installed and checked for safety. Findings: Linens were uncovered and not protected from dust and other contaminants.<br/>Corrective Action:<br/>On January 30, 2014, linen was properly covered. On or before March 3, 2014, the IC 1.22 Linen Handling and Storage policy was reviewed to ensure it appropriately identified the required standards of practice.<br/>Education: On or before March 3, 2014, appropriate Supply Chain Department staff were reeducated on the policy with emphasis on the importance of ensuring clean linens are covered to prevent contamination by dust.<br/>Monitoring: Periodic random observations will take place to assure appropriate procedures are followed so the deficiency is corrected and will not recur.<br/>Responsible Party: Vice President of Supply Chain Management<br/>Findings: MH dirty linen processing area did not have a handwashing sink. Corrective Action (s): The Methodist Hospital Facilities team has solicited an estimate for the installation of a handwashing sink in the dirty</p> |                      |   |

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|   | <p>5. On 1-28-14 at 9:30 am, in the presence of employee #A23, it was observed in the biohazardous waste storage area of Methodist Hospital there was considerable trash on the floor and outside the doorway. The trash consisted of plastic, cardboard and other general refuse.</p> <p>6. On 1-28-14 at 10:15 am, in the presence of employee #A23, it was observed in the clean linen receiving area of Methodist Hosital, there were 19 shelves of clean linen which were not covered and protected from dust and other contaminats.</p> <p>7. Review of Infection Control Policy#: IC 1.22, effective May 20211, indicated all clean linens temporarily stored in the receiving area must be covered and</p> |   | <p>linen processing area. An estimate for the work was provided by Leach &amp; Russell Mechanical on February 28, 2014. The sink should be installed by April 1, 2014. Education: Beginning in April 2014, appropriate staff members will be reeducated on the importance of washing hands when they come in direct contact with soiled linens according to the IC 1.22 Linen Handling and Storage policy.<br/>Responsible Person: Hospital Maintenance Administrator</p> |                      |   |

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| S000556            | <p>protected from dust and other contaminants.</p> <p>8. On 1-28-14 at 10:10 am, in the presence of employee #A23, it was observed in the dirty linen area of Methodist Hospital there was no handwashing sink.</p> <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(b)</p> <p>(b) There shall be an active, effective, and written hospital-wide infection control program. Included in this program shall be 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 policy and procedure review, document review, and staff interview, the facility failed to ensure that an active infection control plan was initiated related to the lack of use of a disinfectant on the floors of patient rooms, and related to the oversight of off site location contracted housekeeping staff.</p> <p>Findings:<br/>1. review of the policy and procedure "Daily Cleaning Order", policy number E.S. (environmental services) #1, last</p> | S000556       | <p>Tag S 556 Rule 410 IAC 15-1.5-2 Findings: Saxony: Lack of use of disinfectant on floor of patient rooms and Isolation room discharge and terminal cleaning. Findings: Saxony: Lack of oversight of off site location contracted housekeeping staff. Corrective Action(s): On or before February 27, 2014, Saxony reviewed and adopted AHC EVS policies and procedures so cleaning would be standardized going forward. Additionally, Saxony contracted EVS changed the cleaning floor solution to an AHC approved</p> | 03/02/2014           |

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|   | <p>dated 9/9/13, indicated:</p> <p>a. on page two under item #5. "Floor", it reads: "...Wet Mop Floor Obtain necessary equipment, materials and chemicals (microfiber mop and tray with approved floor cleaner),...The hospital approved disinfectant must be used if there is a blood or body fluid spill or in high risk areas (Surgery, Labor and Delivery, Cath Labs, Bone Marrow Transplant, GI Lab and Intervention Radiology)..."</p> <p>2. review of the Sodexo (contracted cleaning company at Saxony hospital) cleaning process document titled "Method of the Week"--"Patient Room - Discharge Cleaning" (no policy number or date), indicated:</p> <p>a. under "Procedure", in item #41., it reads: "Damp mop the floor with GC 31 Neutral Cleaner."</p> <p>3. review of the Sodexo (contracted cleaning company at Saxony hospital) cleaning process document titled "Method of the Week"--"Isolation Room Discharge and Terminal Cleaning" (no policy number or date), indicated:</p> <p>a. under "Procedure", in item #2, it reads: "Follow the instructions in normal Patient Room Discharge Cleaning:..."</p> |   | <p>solution which was also improved by Infection Control. Contracted EVS service staff will be oriented by Saxony or AHC EVS so cleaning procedures will be consistent throughout, including but not limited to : high and low dusting procedures, appropriate cleaning of isolation rooms, and both procedures and sequence of procedures. Monitoring: Beginning in March, periodic random observations will take place to ensure appropriate cleaning procedures are followed and appropriate products are used. Responsible Person: Saxony Program Manager of Quality, Risk, and Compliance Findings: CICC East: Findings: failure to delineate which cleaning product is being used by GSF EVS contractor to clean site. ***Clarification of finding: failure of EVS contractor to use bleach for terminal cleaning of patient isolation rooms. Clarification: CICC East does not have patient isolation rooms they only have private rooms so this part of the finding is not accurate and should be revised. Corrective Action (s): On or before March 2, 2014, GSF vendor will ensure that product used to clean facility is on the AHC IC approved cleaner list. Further, CICC management will ensure that GSF contractor reviews and follows AHC EVS policies and procedures to standardize cleaning throughout</p> |   |  |   |  |

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|   | <p>4. review of a page from the document "Guidelines for Environmental Infection Control in Health-Care Facilities" dated 2003 with "Recommendations of CDC (centers for disease control and prevention) and the Healthcare Infection Control Practices Advisory Committee (HICPAC)" that was supplied by infection control staff indicated:</p> <p>a. "Extraordinary cleaning and decontamination of floors in health-care settings is unwarranted. Studies have demonstrated that disinfection of floors offers no advantage over regular detergent/water cleaning and has minimal or no impact on the occurrence of health-care-associated infections...Nevertheless, health-care institutions or contracted cleaning companies may choose to use an EPA (environmental protection agency) registered detergent/disinfectant for cleaning low-touch surfaces (e.g., floors) in patient-care areas because of the difficulty that personnel may have in determining if a spill contains blood or body fluids (requiring a detergent/disinfectant for clean-up) or when a multi-drug resistant organism is likely to be in the environment..."</p> <p>5. at 1:55 PM on 1/29/14, interview with staff members #70, the quality/risk/infection staff member at</p> |   | <p>the AHC. Findings: GSF procedure sequence for low dusting and then high dusting was inappropriate. Corrective Action (s): CICC management will ensure that GSF contractor reviews, follows and is held accountable for compliance with AHC EVS policies and procedures to standardize cleaning throughout the AHC. Findings: GSF EVS staff had not been oriented to AHC EVS policies and procedures and IC expectations. CICC management failed to monitor the cleaning staff and processes to ensure they met applicable standards. Corrective Action (s): EVS AHC policies and procedures were reviewed and provisionally approved by the Infection Control Committee on February 27, 2014. Then the policies were officially approved by the Infection Control Committee by electronic vote on March 7, 2014. Monitoring: Periodic random observations will occur to ensure appropriate AHC EVS policies and procedures are followed by the contractor and approved cleaning products are used. Responsible Person: CICC Manager</p> |                      |   |

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|   | <p>Saxony, #78, the interim director of EVS (environmental services), #82, the facility/health system interim infection preventionist, and #83, the infection preventionist for off site facilities, indicated:</p> <ul style="list-style-type: none"> <li>a. the quality/risk/infection staff member at Saxony should be monitoring the cleaning staff at that facility</li> <li>b. the E.S. #1 policy and the Sodexo documents indicate that only a neutral cleaner will be used on patient rooms after discharge, including isolation rooms of discharged patients, not a disinfectant</li> <li>c. per staff member #82, the CDC considers all floors dirty and only a neutral cleaner is required (see #4 above)</li> <li>d. it cannot be determined by housekeeping staff whether blood or body fluids may have been present on the floor during a patient's hospital stay, nor can it be determined if multi-drug resistant organisms were present in the environment</li> <li>e. the use of only a neutral cleaner for terminal cleaning of patient rooms, especially isolation rooms, is not effective in protecting future patients from the possibility of exposure to pathogens</li> </ul> <p>6. review of the GSF (unknown</p> |   |   |   |  |   |  |

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|   | <p>meaning of acronym) for contracted housecleaners at the Cancer Center East contract indicated:</p> <p>a. the document titled "Exam Rooms/Treatment Rooms" indicates that cleaning staff are to:</p> <p>I. "Daily"--"Wet mop floor in accessible areas..."</p> <p>II. "Dust all low reach areas" and then to "Dust all high reach areas within reach"</p> <p>b. the document titled "Control Rooms/X-Ray Rooms/Infusion Rooms" indicates that cleaning staff are to:</p> <p>I. "Daily"--"Wet mop floor in accessible areas..."</p> <p>II. "Dust all low reach areas" and then to "Dust all high reach areas within reach"</p> <p>c. there were 14 pages of various product types that could be used at the facility for cleaning purposes</p> <p>7. at 2:30 PM on 1/29/14, interview with staff members #70, the quality/risk/infection staff member at Saxony, #78, the interim director of EVS (environmental services), #82, the facility/health system interim infection preventionist, and #83, the infection preventionist for off site facilities, indicated:</p> <p>a. it cannot be determined which product GSF is using at the Cancer</p> |   |   |   |  |   |  |

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|   | <p>Center East location from the 14 pages found in the contract document</p> <p>b. the infection control committee did not approve any of the products used for cleaning and disinfecting by either the contracted Sodexo company at Saxony hospital, or the GSF company at the Cancer Center East</p> <p>c. the infection control committee has not approved the EVS policies related to cleaning processes for facilities</p> <p>d. per staff member #82, the terminal cleaning of isolation rooms of patients with C-Diff are to be cleaned using a bleach solution, including the floors</p> <p>e. the E.S. #1 cleaning policy does not indicate the use of bleach for the cleaning of isolation patient rooms of those with C-Diff</p> <p>f. the GSF cleaning processes, as listed in 6. above, indicate doing low reach dusting and then following up with high dusting--this is incorrect as high dusting would contaminate the already cleaned areas of "low dusting" (the process should be reversed)</p> <p>g. staff member #83 has not been orienting or monitoring the cleaning staff and processes at the off site locations</p> |   |   |   |  |   |  |

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| S000588   | <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(f)(3)(B)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:<br/>(3) The infection control committee responsibilities shall include, but not be limited to, the following:</p> <p>(B) Recommending corrective action plans on identified problems, reviewing outcomes, and assuring resolution.</p> <p>Based on review of the 2013 infection control meeting minutes, and interview, the infection control committee failed to ensure the follow up of actions and recommendations identified at their meetings held through out the year.</p> <p>Findings:<br/>1. Review of the 2013 Infection Control Committee meeting minutes indicated:<br/>a. at the January 24 meeting it was listed under "Miscellaneous" that: "In the month of December there were minimal exceedances of the upper limit of 60% relative humidity in the Ors [sic] (operating rooms) for Methodist, University and Riley." (in the Action/Responsibilities" section of the minutes there was no documentation or notation made)<br/>b. the March 28 meeting listed under</p> | S000588   | <p>Tag S 588 Rule 410 IAC 15-1.5-2 Findings: Failure to ensure the follow-up of actions and recommendations identified at the IC Committee meeting held throughout the year. (OR humidity, process for identification of clean and dirty equipment, refrigerator and ice machine cleaning, Steraplex disinfectant trial, documentation of curtain cleaning schedule, and CHG bathing.)Corrective Action (s): On February 27, 2014, the Infection Control Leadership ensured that all discussions will be documented with actions, recommendations, and follow-up along with identification of the responsible person's title in the Infection Control Committee meeting minutes. Monitoring: Beginning in March, Infection Control Leadership will review Infection Control Committee meeting minutes for actions,</p> | 02/27/2014  |  |   |  |

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|   | <p>"Miscellaneous" that: "In the month of February there were minimal exceedances of the upper limit of 60% relative humidity in the ORs for Methodist and University. Riley had some issues with their reporting data so there are no reports for this month." (in the Action/Responsibilities" section of the minutes there was no documentation or notation made)</p> <p>c. in the May 23 meeting it was reported: "In the month of April there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist and University. Riley had 7 total alarms for April." (in the Action/Responsibilities" section of the minutes there was no documentation or notation made)</p> <p>d. at the June 27 meeting, it was noted: "In the month of May there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist, University and Riley." (in the Action/Responsibilities" section of the minutes there was no documentation or notation made)</p> <p>e. at the August 22 meeting, it was documented: "In the month of July there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist, University and Riley." (in the "Action/Responsibilities section, it reads: "to address humidity</p> |   | <p>recommendations, and a designated responsible person for follow-up to ensure the documentation is complete. Responsible Person: Interim Director of Infection Prevention and Control</p> |   |  |   |  |

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|   | <p>issues in OR" with no specificity noted)</p> <p>f. at the September 26 meeting, it was noted: "In the month of August there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist, University and Riley." (no documentation in the "Action/Responsibilities" section)</p> <p>g. at the November 21 meeting, documentation reads: "In the month of October there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist, University and Riley." (no documentation of follow up or notation in the "Action/Responsibilities" section)</p> <p>h. at the December 19 meeting, the minutes read: "In the month of November there were numerous exceedances of the upper limit of 60% relative humidity in the ORs for Methodist and University. Riley had three (3) exceedances."</p> <p>2. at 3:00 PM on 1/29/14, interview with staff members #82, the interim infection control director for the center, #84, the ICP (infection control preventionist) for Riley, and #85, the ICP for University and Methodist hospitals, indicated:</p> <p>a. the meeting minutes do not indicate discussion of the excesses of 60% humidity in the OR suites, what actions</p> |   |   |   |  |   |  |

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|                    | <p>were being taken to prevent/reduce this issue or whose responsibility this is</p> <p>b. the August meeting did indicate "to address humidity issues in OR" but was not specific as to who would do this, how this would occur, what to do about this continuing/recurring problem</p> <p>c. reporting of a problem with humidity in the OR suites for one year with no resolution or indication of attempts to resolve the issue is ineffective</p> <p>3. Review of the 2013 Infection Control Committee meeting minutes indicated:</p> <p>a. the March 28 meeting minutes read in the "Topic" section: "Clean &amp; Dirty Equipment" and indicated in the "Discussion" area: "One of the items identified during EOC (environment of care) rounds and various other rounds, has been how to identify clean and dirty equipment. There are a variety of current methods such as clear plastic bags being placed over clean equipment. There is a desire to standardize this process across the AHC (academic health center). Committee input was requested." (in the "Action/Responsibilities" section, it read: "Ideas and suggestions can be sent to IC (infection control) for consideration."</p> |               |   |                      |

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|   | <p>b. the March 28 meeting minutes read in the "Topic" section: "Refrigerator &amp; Ice Machines": and indicated in the "Discussion" area: "Committee input was requested and discussion occurred on the monitoring, cleaning, and stocking of pantry refrigerator and freezers. There is various practices occurring and the desire is to standardize this process." (In the "Action/Responsibilities" section, it was noted: "Ideas and suggestions can be sent to IC for consideration.")</p> <p>c. the March 28 meeting minutes read in the "Topic" section: "Infection Prevention Activities": and indicated in the "Discussion" section: "Steraplex disinfectant to be trailed [sic--trialed] on two units at both UH and MH. This product has EPA (environmental protection agency) C. diff claim. The product is fairly new to market and does not currently have a dispensing mechanism and must be manually mixed. Part of the trial will focus on the ability to operationalize this piece until the company develops a dispenser." (In the "Action/Responsibilities" section, it reads: "Will report back the results of the trial and next steps.")</p> <p>4. at 3:00 PM on 1/29/14, interview with staff members #82, the interim infection control director for the center,</p> |   |   |   |  |   |  |

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|   | <p>#84, the ICP for Riley, and #85, the ICP for University and Methodist hospitals, indicated:</p> <p>a. there was no further discussion or notation made in any meeting of the infection control committee, related to the ability to distinguish between clean and dirty equipment, or the cleaning of refrigerator/freezers, after the March 28 meeting through the end of the year, including the December 19 meeting</p> <p>b. there was no further report or discussion of the Steraplex product being trialed, that had been mentioned at the March meeting, through out the remainder of the 2013 meetings of infection control</p> <p>5. at the June 27 meeting of the infection control committee, it was noted in the topic section "Environmental Services Water and Air Quality Reports": in the "Discussion" section: "Records are currently not being kept on curtain changed after Contact and Enteric isolation..." (In the "Action/ Responsibilities" section, it reads: "EVS will work to develop reporting documentation and will present in the future.")</p> <p>6. at 3:00 PM on 1/29/14, interview with staff members #82, the interim infection control director for the center,</p> |   |   |   |  |   |  |

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|   | <p>#84, the ICP for Riley, and #85, the ICP for University and Methodist hospitals, indicated:</p> <p>a. there was no further report or presentation by EVS staff, regarding the development of a tool and reporting related to the changing of curtains after Contact and Enteric isolation patients are discharged, at any other infection control meetings through out the remainder of 2013</p> <p>7. at the September 26, 2013 infection control meeting it was noted in the "Topic" section: "Infection Prevention Activities", and in the "Discussion" section: "CHG Bathing..." (chlorhexadine bathing--a basin less bathing product) and in the "Action/Responsibilities" section, it reads: "Meeting today with University and Methodist regarding universal decolonization process. Also, meeting regarding housewide CHG bathing at Riley. Will present update at the next Infection Prevention Committee Meeting."</p> <p>8. at 3:00 PM on 1/29/14, interview with staff members #82, the interim infection control director for the center, #84, the ICP for Riley, and #85, the ICP for University and Methodist hospitals, indicated:</p> |   |   |   |  |   |  |

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| S000594            | <p>a. there was no follow up to the CHG bathing product at either the November or December infection prevention/control committee meeting, as was stated in September would occur</p> <p>b. it is not clear, due to the lack of documentation within the meeting minutes, that issues/concerns presented to the infection control committee are being acted upon, followed up on, and reported back to the infection control committee for closure or further action</p> <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(f)(3)(D)(ii)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:<br/>(3) The infection control committee responsibilities shall include, but not be limited to, the following:<br/>(D) 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>(ii) Universal precautions, including infectious waste management.</p> <p>Based on document review, observation and interview, the infection control (IC) committee failed to ensure that handling and disposal of infectious waste and trash by environmental services (EVS)</p> | S000594       | Tag S594 Rule 410 IAC 15-1.5-2Findings: UH- facility failed to ensure appropriate handling and disposal of infectious waste and trash by EVS. The Waste Segregation and | 02/03/2014           |

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|   | <p>was performed in compliance with State law and accepted standards of practice.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Title 410 (Indiana Administrative Code) IAC 1-3-10. "Infectious Waste" defined : (a) "Infectious waste ... includes ... (6) Other waste that has been intermingled with infectious waste."</li> <li>Title 410 IAC 1-3-23. "Written policies, procedures" defined: "All persons and facilities subject to this rule shall ... (2) provide necessary instruction and materials, <i>including protective garmets</i> ...prior to giving a person an assignment where contact with infectious waste is likely ..."</li> <li>Title 410 IAC 1-3-25. "Storage" defined: "If infectious waste is stored prior to final disposal, all persons subject to this rule shall ... (3) disinfect reusable containers for infectious waste each time that they are emptied, unless the surfaces of the reusable containers have been protected from contamination by disposable liners, bags, or other devices that are removed with the infectious waste."</li> <li>The policy/procedure Waste Segregation and Disposal Procedures</li> </ol> |   | <p>Disposal policy and procedure failed to indicate an Infection Control Committee approved process for disposing of general refuse intermingled with infectious waste including protective garments due to potential contact with infectious waste by EVS personnel. Failed to indicate a process to detect when an infectious waste bag had failed, leaked, or spilled before the container was emptied. Failed to indicate a process for disinfecting reusable containers for storing and transporting general refuse and infectious waste each time they are emptied. Corrective Action (s): On February 27, 2014, The Waste Segregation and Disposal policy and procedure was reviewed and provisionally approved by the Infection Control Committee. The policy received electronic approval on March 7, 2014. On or before January 29, 2014, all appropriate EVS staff members were reeducated emphasizing the importance of adhering to PPE requirements while handling and disposing of infectious waste and trash. Additionally, beginning March 7, 2014, cart liners are changed every time a cart is emptied. Monitoring: Beginning March 2014, these areas will be monitored on an ongoing basis during EVS rounding to ensure the deficiency has been corrected and will not recur, i.e. PPE is doned appropriately and cart</p> |   |  |   |  |

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|                    | <p>(approved 7-12) provided in response to a request on 1-28-14 for EVS policies/procedures regarding general refuse and infectious waste handling and disposal indicated the following:</p> <p>"General Refuse ...small containers ...may be lined with brown, black, or <u>clear</u> plastic liners. Large containers will be lined with <u>clear</u> or black liners ... general refuse can be carried in the same cart as bio-hazardous (infectious) waste, only if ...all waste in the cart be in intact, sealed bags of appropriate color, and if a bag should fail, open, or spill its contents in any way, all contents are now considered to be biohazardous (infectious), and disposed of as such ..."</p> <p>"Infectious Waste ...place infectious waste (non-sharps) into covered containers labeled ' Infectious Waste - Biohazard ' with the biohazard symbol. These containers are to be lined with <u>clear</u> or red plastic bags labeled as 'Contaminated Waste' with the biohazard symbol ..."</p> <p>The policy/procedure failed to indicate an Infection Control committee-approved process for disposing of general refuse intermingled with infectious waste <i>including protective garmets</i> due to potential contact with infectious waste by EVS personnel, failed to indicate a process to detect when an infectious waste bag had</p> |               | liners changed.Responsible Person: Director of Environmental Services   |                      |

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|   | <p>failed, leaked or spilled <b>before</b> the container was emptied and failed to indicate a process for disinfecting reusable containers for storing and transporting general refuse and infectious waste each time they are emptied.</p> <p>5. During a tour on 1-28-14 at 1225 hours, in the area of the University Hospital (UH) facility services trash compactor and Sani-Pack infectious waste sterilizer, the following condition was observed: an EVS personnel removing bags of general refuse from a large red transport container marked as biohazardous waste. The EVS staff was using only gloves for personal protective equipment (PPE) and no barrier gown or eye protection was present and in use against potential contact with infectious waste.</p> <p>6. During an interview on 1-28-14 at 1215 hours, EVS supervisor A21 confirmed that UH EVS staff transport both medical (infectious) waste and general refuse together in the same cart from patient care areas to the compactor and Sani-Pack room. EVS supervisor A21 indicated that each biohazardous cart used for trash and infectious waste transport is emptied manually by EVS personnel at the compactor and</p> |   |   |   |  |   |  |

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| S000600            | <p>Sani-Pack area. Supervisor A21 indicated that EVS staff change the clear biohazardous cart liner if soiled or torn and indicated that the carts are not routinely washed unless obviously soiled or foul odor is identified.</p> <p>7. During an interview on 1-29-14 at 1410 hours, the UH infection prevention nurse A28 confirmed the waste segregation and disposal policy/procedure failed to indicate an IC-approved process for endpoint disposal of intermingled refuse and infectious waste, liner changes for biohazardous waste carts, and PPE requirements for EVS staff when contact with infectious waste is likely.</p> <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(f)(3)(D)(v)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:<br/>(3) The infection control committee responsibilities shall include, but not be limited to, the following:<br/>(D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:<br/>(v) Reuse of disposables.</p> |               |   |                      |

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|   | <p>Based on document review, observation and interview, the infection control (IC) committee failed to ensure that handling and storage of single-use or disposable devices awaiting reprocessing or re-sterilization was performed in accordance with facility policy/procedure and accepted standards of practice.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>The policy/procedures titled Reprocessing or Re-Sterilization of Single Use or Disposable Device (approved 11-12) and Waste Segregation and Disposal (approved 7-12) failed to indicate an IC-approved process for disinfecting, handling and storage of single use medical devices after use involving invasive procedures with a patient and before transport to a Food and Drug Administration (FDA) approved reprocessor.</li> <li>During a tour on 1-28-14 at 1040 hours, in the area adjacent to the University Hospital (UH) facility services trash compactor and Sani-Pack infectious waste sterilizer, the following condition was observed: (5) closed 18 gallon dark green hazardous materials containers with biohazardous signage and the name of a medical product</li> </ol> | S000600   | <p>Tag S 600 Rule 410 IAC 15-1.5-2 (f) (3) (D) (v) Findings: UH- failed to ensure handling and storage of single use devices awaiting reprocessing was performed in accordance with requisite policy, procedures, and standards. Corrective Action (s): On or before January 31, 2014, the single use devices waiting to be re-processed were removed from the area. Education: On or before, February 27, 2014, staff were reeducated and it was reemphasized single use devices waiting for reprocessing should be disinfected and stored in a secure location until disposition to FDA approved vendor. Responsible Person: Director of Environmental Services</p> | 02/27/2014  |  |   |  |

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|   | <p>manufacturer headquartered in Kalamazoo, Michigan. The containers were observed in an unsecured hallway under a sign labeled biohazardous waste.</p> <p>3. During an interview on 1-28-14 at 1040 hours, facilities manager A14 confirmed that the area was not an appropriate and secure location for storing reprocessing totes until transport to an FDA-approved reprocessor.</p> <p>4. During an interview on 1-30-14 at 0915 hours, staff A1 indicated that the medical devices contained in the sealed containers were awaiting disinfection prior to final disposition. Staff A1 indicated that it was determined that the devices were collected for reprocessing per agreement with the manufacturer and indicated that a different provider is the current reprocessor destination for the facility. Staff A1 confirmed that the current process requires sterilization of the medical device prior to packaging and return to the reprocessing facility and confirmed that the (5) medical device reprocessing totes had been moved to a secure location.</p> |   |   |                      |   |

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| S000608   | <p>410 IAC 15-1.5-2<br/>INFECTION CONTROL<br/>410 IAC 15-1.5-2(f)(3)(D)(ix)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:<br/>(3) The infection control committee responsibilities shall include, but not be limited to, the following:<br/>(D) 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 appropriate for work settings.</p> <p>Based on policy and procedure review, observation, and staff interview, the infection control committee failed to ensure the implementation of its policy related to surgical dress code for more than 6 staff members in the surgery area of Riley hospital.</p> <p>Findings:<br/>1. review of the policy and procedure "Dress Code: Perioperative Practice Domain", policy number POS 1.07, with an approval and effective date of October 2012, indicated:<br/>a. under section "V. Policy Statements", it reads on page 4., under section C. "Head/Face": "...4....Masks should not be worn hanging around the</p> | S000608   | <p>Tag: S 608 Rule 410 IAC 15-1.5-2(f) (3) (D) (ix) Findings: Failure to ensure implementation of surgical dress code policy. Corrective Action(s): Riley Perioperative Services reviewed its policy to ensure it appropriately identified the required standards of practice. On or before February 21, 2014, signs were posted on all exit doors of the OR area to remind staff to remove all disposable hats, masks and shoe covers. Education: On or before February 28, 2014, POS 1.07 Dress Code: Perioperative Practice Domain was distributed and conspicuously posted for all staff to review. All Riley Perioperative employees reviewed the policy and signed an attestation explaining they</p> | 02/28/2014  |  |   |  |

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|   | <p>neck..."</p> <p>2. at 1:10 PM on 1/28/14, while on tour of the Riley surgery area in the company of staff members #80, the RN (registered nurse)/surgery director, and #81, the RN director/manager of the NICU (neo-natal intensive care unit) at the facility and tour guide, it was observed that:</p> <p>a. an anesthesiologist was in the anesthesia work room, sitting at a computer, with their surgical mask down about the neck</p> <p>b. three other staff members ambulated in the hallway outside the anesthesia work room with their surgical masks dangling about the neck</p> <p>3. at 1:50 PM on 1/28/14, while on tour of the Riley surgery area in the company of staff members #80, the RN/surgery director, and #81, the RN director/manager of the NICU at the facility and tour guide, it was observed that two pharmacy technicians were in the pharmacy area with their surgical masks hanging under their hair, at the base/back of their necks</p> <p>4. interview with staff member #80 during the tour, while other staff were also noted to have their masks down about the neck, indicated that this was not to occur, facility policy requires that</p> |   | <p>understood the requisite expectations for practice and would incorporate them immediately. Beginning February, 28, 2014, education regarding policy and performance expectations will be added to the curriculum for orientation for relevant staff within the Riley Perioperative Services. Monitoring: Periodic random observations will take place to assure appropriate policies and procedures are followed. If performance gaps are identified, staff will receive immediate retraining to ensure the deficiency has been corrected and will not recur. Responsible Person: Clinical Director of Perioperative Services</p> |   |  |   |  |

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| S000788            | <p>masks not be left dangling about the neck</p> <p>410 IAC 15-1.5-4<br/>MEDICAL RECORD SERVICES<br/>410 IAC 15-1.5-4(i)(9)</p> <p>(i) Emergency service records shall document and contain, but not be limited to, the following:</p> <p>(9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.</p> <p>Based on document review and interview, the facility failed to ensure that Emergency Department (ED) staff followed its policy / procedure Patient Transfer to Another Facility for 2 of 2 ED transfer medical records (MR) reviewed (Patient #11 &amp; 12).</p> <p>Findings include:</p> <p>1. Review of policy / procedure Patient Transfer to Another Facility indicated the following:<br/>"C. Procedure for "Appropriate" Transfer</p> <p>6. Complete the Transfer Form<br/>Note: If the emergency patient has been stabilized before the transfer of if the patient is determined not to have an</p> | S000788       | <p>Tag S 788 Rule 410 IAC 15-1.5-4 (i)(9) Findings: MH- failure to document risk and benefits of transfer as required per policy. Corrective Action (s): On or before February 24th, 2014, MH ED leadership reviewed its policies to ensure they appropriately identified the required standards of practice. Education: On or before February 24th, 2014, all ED staff, providers, and shift coordinators were reeducated via memos and training emphasizing the importance of completion and verification prior to patient transfer that the documentation is accurate and complete. Monitoring: Beginning in February 2014, the ED Quality Coordinator or her designee will audit Transfer Forms to ensure</p> | 02/24/2014           |

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|                    | <p>emergency medical condition but the transfer is to occur, items C. 1-6 are completed for continuity of care." This policy / procedure was last reviewed / revised on 06-13.</p> <p>2. Review of patient #11's MR indicated the patient was transferred from the facility ED to another facility on 05-12-13. Review of the transfer form lacked documentation of the risks and benefits for transfer being documented.</p> <p>3. Review of patient #12's MR indicated the patient was transferred from the facility ED to another facility on 07-03-13. Review of the transfer form lacked documentation of the risks and benefits for transfer being documented.</p> <p>4. On 01-30-13 at 1355 hours, staff #5 confirmed that patient #11 &amp; 12's MR lacked documentation of the risks &amp; benefits being documented.</p> |               | <p>risks and benefits of transfer are documented. The audit process will continue for three consecutive months with expectations for achievement of 90% or greater compliance. Any identified gaps will be immediately discussed with the appropriate ED staff member, provider or shift coordinator on an individual basis for performance improvement. Results of the audit will be communicated through the AHC QAPI process. Responsible Person: Director of Clinical Operations</p> |                      |

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| S000912            | <p>410 IAC 15-1.5-6<br/>NURSING SERVICE<br/>410 IAC 15-15-6 (a)(2)(B)(i)(ii)<br/>(iii)(iv)(v)</p> <p>(a) The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing service furnished or supervised by a registered nurse. The service shall have the following:</p> <p>(2) A nurse executive who is:<br/>(B) responsible for the following:<br/>(i) The operation of the services, including, but not limited to, determining the types and numbers of nursing personnel and staff necessary to provide care for all patient care areas of the hospital.<br/>(ii) Maintaining a current nursing service organization chart.<br/>(iii) Maintaining current job descriptions with reporting responsibilities for all nursing staff positions.<br/>(iv) Ensuring that all nursing personnel meet annual in-service requirements as established by hospital and medical staff policy and procedure, and federal and state requirements.<br/>(v) Establishing the standards of nursing care and practice in all settings in which nursing care is provided in the hospital.</p> <p>Based on document review, observation and interview, the nurse executive failed to ensure that nursing staff followed established Nursing Care Guidelines for Cesarean Delivery and followed policy /</p> | S000912       | Tag S 912 Rule 410 IAC 15-1.5-6 Findings during closed record review: Pediatric patient had an elevated blood sugar with an insulin drip ordered at 2206 and was not started until 0113 | 02/03/2014           |

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|   | <p>procedure Nasogastric and Orogastric Tubes: Placement and Maintenance in Adult Patients for 2 of 3 obstetrical (OB) medical records (MR) and 2 of 2 patients with nasogastric feeding tubes MRs reviewed (Patient #4, 15, 18 &amp; 20), failed to ensure the implementation of the glucometer control/point of care testing policy in 3 areas toured and failed to ensure physician orders were carried out timely for 2 of 7 patients whose closed medical records were reviewed (#N9 and N13).</p> <p>Findings include:</p> <p>1. Review of the Nursing Care Guidelines for Cesarean Delivery indicated the following:<br/>"Delivery / Recovery - Phase II<br/>Assess VS by P, R, BP Q 15 min x 4 until stable, then Q 30 until recovery complete.<br/>Assess patient using Aldrete recovery grading scale; Document score with 1st and last set of VS after vaginal delivery and with each set of VS after Cesarean section."</p> <p>2. Review of patient #4's MR indicated the patient had a Cesarean section on 01-27-14 and the physician ordered the following: Initiate Nursing Care Guidelines for Cesarean Delivery. The</p> |   | <p>with no documented explanation of why it was delayed. Corrective Action (s): When this incident occurred in December 2013, an incident report was filed and immediate action taken. The investigation revealed difficulty in obtaining a second IV access. Education: Immediately after the incident, the ED nurse educator reviewed education for Pediatric ED diabetic patients to ensure it appropriately identified the required standards of practice. Then, ED nurses were reeducated regarding appropriate standards of care for ED patients with diabetes and this information was incorporated into their practice. On December 2, 2013, ED staff were trained on use of an ultrasound guided IV program to help initiation of IV access in a more timely manner. Beginning in January 2014, education regarding treatment of DKA pediatric patients in the ED was added to the curriculum for orientation for relevant staff in the Riley ED. Finally, the Clinical Practice Council is reviewing the PICU algorithm for patients in DKA to develop an algorithm for the ED so common treatments (including IV fluids) can be anticipated for this patient population in the future. Additionally, Riley ED nurses were reeducated to emphasize that whenever care is delayed the reason should be prominently documented in the patient's</p> |                      |   |

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|   | <p>Aldrete recovery grading scale was documented only with the fist set of recovery vital signs.</p> <p>3. Review of patient #15's MR indicated the patient had a Cesarean section on 12-11-13 and the physician ordered the following: Initiate Nursing Care Guidelines for Cesarean Delivery. The Aldrete recovery grading scale was documented only with the fist set of recovery vital signs.</p> <p>4. On 01-28-14 at 1325 hours, staff #66 confirmed that nursing staff do not document the Aldrete recovery grading scale with each set of vital signs during the recovery phase for cesarean section patients.</p> <p>5. Review of policy / procedure Nasogastric and Orogastric Tubes: Placement and Maintenance in Adult Patients indicated the following:<br/>"B. Daily Care and Documentation<br/>6. Document residuals every 4 hours when tube is used for continuous enteral feedings."<br/>This policy / procedure was last reviewed / revised on 09-12.</p> <p>6. Review of patient #15's MR indicated the patient had continuous feedings via a nasogastric tube starting on 11-15-13.</p> |   | <p>medical record. Responsible Person: P-EMTC Clinical Manager Findings: Circumcision checks were not completed per physician order. Corrective Action (s): On or before, February 21, 2014, appropriate NICU staff members were reeducated via email reemphasizing the importance of performing circumcision checks per physician's order at 30 minutes, 1 hour, and 2 hours following the procedure and PRN at diaper changes. Additionally, this information was distributed in the weekly Huddle Update on or before March 6, 2014 and in the March edition of the Newborn Newsletter. Monitoring: Beginning in March 2014, monthly audits are being conducted for at least six consecutive months with expectations of 90% or greater compliance. Any identified gaps will be discussed immediately with NICU nurses on an individual basis for performance improvement. Results of audits will be communicated through the IU Health QAPI program. Responsible Person: NICU Manager Findings: MH-C-Section: An Aldrete score was not documented as completed with each set of vital signs during the recovery phase per policy. Corrective Action (s): On January 28, 2014, IUH Maternity Center policy 1.08 OB Surgical Recovery Care was reviewed and revised to</p> |                      |   |

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|   | <p>The MR lacked documentation of residual checks from 11-22-13 to 11-30-13.</p> <p>7. Review of patient #20's MR indicated the patient had continuous feedings via a nasogastric tube starting on 12-06-13 at 0800 hours and the first residual check was documented on 12-06-13 at 2100 hours.</p> <p>8. On 01-31-14 at 1025 hours, staff #5 confirmed that patient #15 &amp; 20's MR lacked documentation on residual checks being documented.</p> |   | <p>ensure it identified the required standards of practice. The revisions include expectations that OB patients in recovery will be assessed using the Aldrete recovery grading scale and this assessment should be documented with the first and last set of vital signs. This policy revision was reviewed and approved by the AHC OB Professional Practice Committee on February 26, 2014. Education: MH OB staff members will be educated regarding the policy revision and expectations for practice on or before March 5, 2014. Monitoring: Beginning in March 2014, to ensure compliance MH OB will initiate a monthly audit of 10 charts per month for three months to ensure the Aldrete assessments are documented with the first and last set of vital signs per policy. The expectations for compliance will be 90% or greater. Responsible Person: Clinical Director of Women's Services Findings: Nasogastric/Orogastric documentation of residual volumes every four hours during continuous feeding was not completed per policy. Corrective Action (s): MH Director of Clinical Operations for Critical Cares reviewed its policy and procedure to ensure they appropriately identified the required standards of practice. Education: On or before March 17, 2014, staff nurses were reeducated</p> |                      |   |

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|                    |  |               | <p>regarding the policy and expected practice documentation. Beginning in March 2014, education regarding policy and procedure expectations will be added to the curriculum for orientation for relevant staff within the MH critical care units. Monitoring: To ensure compliance, beginning March 2014, MH Critical Care staff will initiate a weekly audit of medical records for three consecutive months with expectations for achievement of 90% or greater compliance. Any identified gaps will immediately be discussed with the critical care nurse on an individual basis for performance improvement. Responsible Person: Director of Clinical Operations for Critical Care Division Findings: Saxony: (Perioperative area)-Glucometer and Point of Care testing-expired glucometer control solutions. Corrective Action: On or before, January 27, 2014, managers reviewed current policy and procedure to ensure they appropriately identified the required standards of practice. Education: On or before January 27, 2014, staff members were reeducated regarding the importance noting on the glucometer control bottles the date opened and expiration dates. Monitoring: To ensure compliance, beginning March 2014, the Perioperative areas will be periodically checked to ensure</p> |                      |

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|   | 9. review of the policy and procedure "Point of Care Testing Program Policy and Procedures", policy number 01.001.13 with a last revision date of 01/26/11, indicated:<br>a. on page 4 under "C. Environment, Equipment, and Safety", it reads: "1. Point-of-Care Testing reagents will be stored according to manufacturer's recommendations for temperature and humidity and documented daily. 2. |   | the glucometer control bottles have not expired. Any identified gaps will be immediately discussed with appropriate staff member on an individual basis for performance improvement. Findings: Saxony: (Short Stay Unit)-2 vials without notation of date opened and expiration date. Corrective Action: On or before January 31st, 2014, the two vials without notation of date opened and expiration date were discarded. Monitoring: To ensure compliance, beginning March 2014, the Short Stay Unit will be periodically checked to ensure the glucometer control bottles have been labeled with the date opened and expiration date. Any identified gaps will be immediately discussed with appropriate staff member on an individual basis for performance improvement. Findings: CICC East: glucometer control solutions had expired. Corrective Action: On January 30, 2014, the glucometer testing at this site was discontinued. |                      |   |

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|   | <p>Containers will be marked with open dates and expiration dates as recommended by the manufacturer..."</p> <p>10. review of the Accu chek Inform II documentation related to control solutions indicated:<br/>a. the control solutions have a "three month stability once opened"</p> <p>11. at 11:40 AM on 1/27/14 while on tour of the Saxony hospital peri operative area in the company of staff members #63, the quality/risk/infection staff member, and #69, the nurse manager of peri op and surgery, it was observed in the nursing station that the glucometer control solutions had expired 1/17/14</p> <p>12. at 11:40 AM on 1/27/14, staff members #63 and #67 agreed that the control solutions were expired</p> <p>13. at 12:35 PM on 1/27/14, while on tour of the Saxony hospital short stay (surgery) unit in the company of staff member #63, the quality/risk/infection staff member, it was observed that the glucometer control solutions lacked notation on the vials (2) of the date when opened</p> <p>14. on 1/28/14 at 9:30 AM while</p> |   |   |   |  |   |  |

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|   | <p>touring the off site Cancer Center East location in the company of staff members #71, an accreditation/regulatory staff member, and #75, the facility manager/director, it was observed in the lab area that the glucometer control solutions had expired 1/23/14</p> <p>15. at 9:30 AM on 1/28/14, interview with staff member #75 indicated the glucometer control solutions were expired as stated in 5. above</p> <p>16. Review of the medical record for patient #N9 indicated a circumcision was completed at 2130 on 12/16/13 and physician's orders to check circumcision site at 30 minutes, 1 hour, and 2 hours following the procedure and PRN (as needed) at diaper changes. Nursing documentation only indicated a check of the site at 2200 on 12/16/13, 30 minutes after completion of the procedure.</p> <p>17. Review of the medical record for patient #N13 indicated an ED (Emergency Department) visit at 2020 on 12/10/13 for a chief complaint of high blood sugars, vomiting, and diarrhea. A point of care blood sugar was recorded as 594 (normal range 60-100) at 2055 on 12/10/13 and an actual lab blood sugar of 610 at 2100 on</p> |   |   |   |  |   |  |

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|   | <p>12/10/13. The record indicated a physician order from 2206 on 12/10/13 for an insulin intravenous drip, but documentation indicated the insulin drip was not started until 0113 on 12/11/13 (over 3 hours later) with no explanation for the delay.</p> <p>18. The facility policy "Medication Order Turn Around Time Standards", effective November 2011. indicated, "A. STAT order: 1. The order should be written as 'STAT'. 2. The nurse must make their pharmacist aware of the STAT order by verbally communicating the need directly to a pharmacist. 3. The pharmacist receiving the STAT call from the nurse is responsible for assuring the product is on the unit within 15 minutes. ...C. Routine orders: 1. Routine orders are processed and medications are delivered to the nursing unit within two (2) hours."</p> <p>19. At 3:15 PM on 01/30/14, staff member A20, who was navigating the EMR (Electronic Medical Record), confirmed the findings regarding the circumcision for patient #N9.</p> <p>20. At 10:50 AM on 01/31/14, staff member A22 indicated all orders were considered STAT in the ED, whether or not the physician made the designation.</p> |   |   |   |  |   |  |

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| S000952            | <p>He/she indicated medications should be delivered STAT to the ED.</p> <p>21. At 11:55 AM on 01/31/14, staff member A21 confirmed the medical record findings for patient #N13 and could not explain the delay in treatment of a critically elevated blood sugar.</p> <p>410 IAC 15-1.5-6<br/>NURSING SERVICE<br/>410 IAC 15-1.5-6(d)</p> <p>(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6). Based on policy/procedure review, transfusion record review, and staff interview, the facility failed to administer blood transfusions in accordance with approved medical staff policies and procedure for 4 of 11 patients.</p> <p>Findings include:</p> <p>1. The Blood and Blood Component Administration policy, HM1.01AP, revised 06/12, read:<br/>"Procedures</p> | S000952       | <p>Tag S 952 Rule 410 IAC 15-1.5-6 Findings: Post transfusion vital sign documentation was incomplete and pre-transfusion vital signs were not documented per policy. Corrective Action (s): On or before March 2, 2014, nurses were reeducated via the Quality and Safety Brief regarding the importance of completion of transfusion vital sign documentation as well as emphasis on taking pre-transfusion vital signs 60 minutes before the blood transfusion is initiated. This information was also discussed</p> | 03/02/2014           |

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|                    | <p>Complete the transfusion document. ALL BLANKS MUST BE FILLED OUT."</p> <p>2. In review of five patients receiving blood units, 1 of these received-units did not have complete documentation, per policy:<br/>Patient #2<br/>Unit given on 10/01/13 at _____:<br/>The post transfusion vitals were missing the nursing signature and time of completion.</p> <p>3. On 1/29/14 at 2:45 p.m., staff member #1 conferred the above-listed patient had been administered blood units without complete vital documentation per policy.</p> <p>4. On 1/29/14 between 12:30 p.m. and 3:30 p.m. review of a policy/procedure titled: "Indiana University Health, BLOOD AND BLOOD COMPONENT ADMINISTRATION, Policy#: HM1.01AP, Effective Date: June 2012," which stated: "B. Minimum Documentation Requirements 1. Pre-transfusion Vital Signs: record vital signs prior to transfusion initiation, including: temperature, heart rate, respiration and blood pressure."</p> <p>5. On 1/29/14 between 12:30 p.m. and 3:30 p.m. review of 6 transfusion records demonstrated facility staff failed</p> |               | <p>during shift/safety huddles daily for the week of March 2, 2014. Additionally, for six weeks beginning on March 2, 2014, a documentation checklist will be included with all blood products as just in time staff education and a reminder of transfusion documentation requirements. Monitoring: Beginning in March 2014, Blood Bank will audit tranfusion documentation completion and feedback will be provided to facility based regulatory leaders for inclusion in their Professional Practice Council meetings. Responsible Person: Executive Director of Nursing Professional Practice and Operational Improvement</p> |                      |

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| S001024            | <p>to follow approved medical staff policy/procedure for T#3, T#4, and T#5 (T=Transfusion) by failing to take the Pre-transfusion Vital Signs. Records indicated Pre Vital Signs were taken as the transfusions were initiated.</p> <p>6. On 1/29/14 between 12:30 p.m. and 3:30 p.m. SP # 35 (SP=staff person) acknowledged T#3, T#4, and T#5 did not have Pre-transfusion Vital Signs taken to follow approved medical staff policy/procedure.</p> <p>410 IAC 15-1.5-7<br/>PHARMACEUTICAL SERVICES<br/>410 IAC 15-1.5-7 (d)(2)(C)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or destruction.</p> <p>Based on document review, observation and interview, the department of pharmacy failed to follow its policy/procedures regarding the quarantine of outdated and unusable</p> | S001024       | Tag S 1024 Rule 410 IAC 15-1.5-7 (d) (2) (C) Finding: Separation of expired medication in inpatient pharmacy at University Hospital. Corrective Action: On January 28, 2014, the | 02/06/2014           |

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|   | <p>drugs for 72 expired bottles of Dantrolene observed at the University Hospital (UH) inpatient pharmacy.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. The policy/procedure Expired Pharmaceutical Product and Patient own Medication Disposal (approve 11-13) indicated the following: " The expired pharmaceutical products that are removed from operational use will be isolated in a designated area within the pharmacy department. "</li> <li>2. During a tour on 1-28-14 at 1000 hours, in the inpatient pharmacy room R-093 of University Hospital (UH), the following condition was observed: boxes of unexpired anesthetic inhalation agents including Desflurane, Halothane, Isoflurane and Sevoflurane were observed on an unlabeled shelf to the left of (2) boxes of 36 bottles each containing Dantrolene with the indication: expired meds.</li> <li>3. During an interview on 1-28-14 at 1000 hours, pharmacy manager A19 confirmed that the designated area for expired medications was located elsewhere in the pharmacy.</li> </ol> |   | <p>expired medication was moved to the designated area in the warehouse. Education: On or before February 6, 2014, employees were reeducated during huddles and staff meetings regarding importance of proper handling and segregation of expired medication from medication that is ready for patient use. Monitoring: This area will be monitored for three consecutive months with expectations for acheivement of 90% or greater compliance. Responsible Person: Director of Pharmacy IU Health University Hospital</p> |                      |   |

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| S001118   | <p>410 IAC 15-1.5-8<br/>PHYSICAL PLANT<br/>410 IAC 15-1.5-8 (b)(2)</p> <p>(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation, interview, policy and procedure review, and manufacturer literature, the hospital created 3 conditions which resulted in a hazard to patients, public or employees as related to an alcohol hand-based sanitizer (ABHS) located directly over a light switch, as related to dirty refrigerators and expired products and regarding warming peritoneal dialysis fluids.</p> <p>Findings:</p> <p>1. On 1-28-14 at 1:30 pm in the presence of employee #A23, it was observed in Rehab Exam Room 3 of the Neuroscience Building at Methodist Hospital, there was an alcohol hand-based sanitizer (ABHS) located directly over a light switch. This posed a fire hazard if the flammable alcohol was sprayed or</p> | S001118   | <p>Tag S 1118 Rule 410 IAC 15-1.5-8(b) (2) Findings: Peritoneal Dialysis fluid was observed in fluid warmer without placement date<br/>Corrective Action: On or before February 28, 2014, the Peritoneal Dialysis fluid will be labeled with an expiration date not to exceed 45 days from the date it is put in the warmer which was consistent with both a literature search and manufacturers recommendations. If solutions are in the warmer at the expiration date, they will be discarded. On March 5, 2014, the CP 1.40 A Peritoneal Dialysis: IU Health Methodist Hospital policy was reviewed and revised to include the new process for labeling dialysate solution for 45 days prior to placing into the warmer. This policy will be reviewed and approved at the March 2014 Policy Steering Group meeting. Education: On or</p> | 02/28/2014  |  |   |  |

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|                    | dropped into the electrical ignition source.   |               | before February 23, 2014, employees were educated regarding the new labeling process and requisite expectations during staff meetings. Charge nurses were educated via email on or before February 27, 2014. Monitoring: Regularly scheduled audits will be conducted to ensure Peritoneal Dialysis fluids are appropriately labeled with an expiration date and are not in the warmer beyond the labeled date. Responsible Person: Nursing Manager B5/C5 Findings: RH-PACU expired Purell hand sanitizer Corrective Action (s): On January 28, 2014, the expired Purell hand sanitizer was discarded. Beginning, March 3, 2014, the Pre/Post Care Unit Charge Nurse or her designee will check expiration dates of hand sanitizers on a weekly basis and discard any that have expired. Additionally, checking for expired hand sanitizers has been added to the PACU departmental checklist to ensure the deficiency has been corrected and will not recur. Responsible Person: Clinical Director of Perioperative Services Findings: RH ED-Refrigerator in patient nourishment area was dirty. Corrective Action (s): On February 26th, 2014, Nursing Quality reviewed and revised the PC SF 1.02 Refrigerator and Freezer Temperature and Monitoring policy to include |                      |

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|                    | 2. at 12:39 PM on 1/27/14, while on tour of the Short Stay (surgical) Unit at Saxony hospital in the company of staff members #66, an |               | instructions for refrigerator cleaning. Education: On February 24, 2014, PSAs and Charge Nurses were educated about the refrigerator cleaning log and expectations for practice that refrigerators are cleaned on a daily basis. Monitoring: Periodic random observations will take place to assure appropriate procedures are followed and refrigerators are clean. If performance gaps are identified, staff will receive immediate retraining to ensure the deficiency is corrected and does not recur. Responsible Person: P-EMTC Clinical Manager Findings: Neuro Science Bldg: Alcohol based hand sanitizer was installed over a light switch in ( Rehab Exam Room #3). Corrective Action(s): On February 28, 2014, a member of the Landmark Healthcare Maintenance staff at the Neuroscience Building was asked to move the hand sanitizer dispenser in Rehab Exam Room #3 so it was no longer located directly above the light switch. On March 3, 2014, the property manager at the Neuroscience Building confirmed the alcohol based hand sanitizer had been moved. Responsible Person: Hospital Maintenance Administrator |                      |

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|   | <p>accreditation/regulatory staff person, #70, the facility quality/risk/infection person, and #69, a registered nurse manager of peri operative services, indicated the pantry refrigerator was dirty with a smeared, dried, liquid on the top glass shelf and debris found in the vegetable drawers</p> <p>3. interview with staff members #66, #69, and #70 at 12:40 PM on 1/27/14 indicated agreement that the pantry refrigerator was dirty and:</p> <p>a. it was unknown the last time it had been cleaned</p> <p>b. there is no routine refrigerator cleaning schedule or log</p> <p>4. at 10:20 AM on 1/28/14, while on tour of the off cite Cancer Center East in the company of staff members #71, an accreditation/regulatory staff member, and #75, the center manager, it was observed in a hallway storage area/closet that 10 vials of 50 ml Sterile Bacteriostatic water had expired November 1, 2013</p> <p>5. at 10:20 AM on 1/28/14, staff member #71 confirmed the expiration of the 10 vials of sterile water listed in 3. above</p> <p>6. at 1:25 PM on 1/28/14, while on tour</p> |   |   |   |  |   |  |

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|                    | <p>of the Riley hospital PACU (post anesthesia care unit) in the company of staff members #80, the RN (registered nurse)/surgery director, and #81, the RN director/manager of the NICU (neo-natal intensive care unit) at the facility and tour guide, it was observed in the housekeeping closet, on top of the housekeeper's cleaning cart, that the Purell hand pump of sanitizing foam had expired 8/11 (August 2011)</p> <p>7. at 1:25 PM on 1/28/14, staff members #80 and #81 agreed that the hand sanitizer had expired</p> <p>8. at 2:35 PM on 1/28/14, while on tour of the Riley hospital ED (emergency department), in the company of staff member #77, the ED director, it was observed in the nourishment area that the refrigerator was dirty under the vegetable drawers with crumbs, debris, and at least one hair</p> <p>9. at 2:35 PM on 1/28/14, interview with staff member #77 indicated:</p> <ul style="list-style-type: none"> <li>a. the refrigerator was dirty as described in 7. above</li> <li>b. the PSA (patient service assoc/assistant) staff are responsible for cleaning the refrigerator</li> <li>c. the PSAs have a daily cleaning sheet/check off that they complete on</li> </ul> |               |   |                      |

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|   | <p>their 8 hour shift and turn in to the nurse manager/supervisor (form titled "Daily P-EMTC PSA Duties")</p> <p>d. the checklist of cleaning is not kept, but discarded after being turned in to the nurse manager--duties not accomplished on one shift may be specifically assigned to the next PSA on duty</p> <p>e. it cannot be determined, due to the lack of documentation, the last time the ED refrigerator had been cleaned</p> <p>10. at 2:40 PM on 1/28/14, review of the two page form: "Daily P-EMTC PSA Duties" indicated on page two, 2/3 of the way down on the page, that "Nourishment room" included: "Clean refrigerator inside..." as a daily duty</p> <p>11. at 1:55 PM on 1/29/14, interview with staff members #70, the quality/risk/infection staff member at Saxony, #78, the interim director of EVS (environmental services), #82, the facility/health system interim infection preventionist, and #83, the infection preventionist for off site facilities, indicated:</p> <p>a. the quality/infection staff member at Saxony should be monitoring the cleaning staff at that facility</p> <p>b. per staff member #78, EVS staff are to be monitored by their supervisors</p> <p>c. some refrigerators are the</p> |   |   |   |  |   |  |

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|                    | <p>responsibilities of various staff, depending on the location of the refrigerator, such as: nursing may be responsible for some, EVS for some, and dietary or pharmacy for others</p> <p>d. there is no facility policy related to cleaning refrigerators in the hospitals or off site locations</p> <p>12. During the tour of the Metabolic/Renal Unit, B5/C5, at 11:00 AM on 01/29/14, accompanied by staff members A3, A12, and A17, seven bags of peritoneal dialysis fluids were observed in a warming cabinet which registered 107 degrees F (Fahrenheit). The temperature monitoring log with the cabinet showed daily checks with the unit usually registering 106- 107 degrees F.</p> <p>13. At 11:05 AM on 01/29/14, staff member A17 indicated the fluids were used fairly quickly, but the bags were not dated to determine length of time in the warmer or to ensure they were used on a first-in/first-out basis. He/she indicated he/she was not aware of any specifications by the manufacturer, Delflex, regarding the length of time the fluids could be in the warmer.</p> <p>14. The facility's policy "Peritoneal Dialysis", effective June 2013, did not discuss any specific temperatures or</p> |               |   |                      |

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|   | <p>length of time in the warmers for the fluids.</p> <p>15. The facility policy "Blanket and Fluid Warmers", effective June 2012, indicated, "1. The temperature of warming cabinets used for fluids only may not exceed 110 degrees F (43 degrees C)." The two References/Citations listed were Perioperative Standards and Recommended Practices from AORN and the Baxter Healthcare Corporation.</p> <p>16. A labeling sheet from the Delflex manufacturer indicated, "...Exposure to temperatures above 25 degrees C/77 degrees F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period."</p> <p>17. An internet search for the Delflex peritoneal dialysis fluids indicated the following information: "Storage Conditions- Store at 20 degrees C to 25 degrees C (68 degrees F to 77 degrees F), excursions permitted between 15 degrees C- 30 degrees C (between 59 degrees F- 86 degrees F) ...Brief exposure to temperatures up to 40</p> |   |   |   |  |   |  |

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| S001124            | <p>degrees C (104 degrees F) may be tolerated provided the mean kinetic temperature does not exceed 25 degrees C (77 degrees F); however, such exposure should be minimized."</p> <p>410 IAC 15-1.5-8<br/>PHYSICAL PLANT<br/>410 IAC 15-1.5-8 (b)(5)(A)</p> <p>(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(5) Provision shall be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(A) Operation, maintenance, and spare parts manuals shall be available, along with training or instruction of the appropriate personnel, in the maintenance and operation of the fixed and movable equipment.</p> <p>Based on policy and procedure review, observation, document review, and interview, the facility failed to implement its policy on blanket warmers in 2 areas toured.</p> <p>Findings:</p> | S001124       | Tag S 1124 Rule 410 IAC 15-1.5-8 Findings: Saxony: hospital failed to implement its policy on blanket warmers in two areas: (Peri-operative area and Cath lab) There was no documentation of monthly internal cleaning of blanket warmers by | 02/16/2014           |

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|   | <p>1 review of the policy and procedure "Blanket and Fluid Warmers", policy number SF 1.10 AP, with an approval date of June 2012, indicated:</p> <p>a. on page two under "VI. Procedures": "A. Warming Cabinets Used for Blankets Only...2. Cleaning: to reduce the spread of infectious agents, the interior of the warmer will be wiped down by environmental Service staff members monthly and when visibly soiled..."</p> <p>2. on 1/27/14 at 11:42 AM while on tour of the Saxony peri operative area in the company of staff members #65, the chief nursing officer, and #70, the quality/risk coordinator and infection preventionist, it was observed that the MEC blanket warmer was dusty in the lower cabinet on the lower shelf (blanket warmer asset #102959 and IU health #500572)</p> <p>3. interview with staff member #70 at 11:45 AM on 1/27/14 indicated it was unknown that the blanket warmers developed accumulated dust</p> <p>4. while on tour of the cath lab at Saxony on 1/27/14, in the company of staff members #70, the quality/risk coordinator and infection preventionist, #73, a cath lab employee, and #66, an</p> |   | <p>EVS staff. Corrective Action (s): On or before February 16, 2014, Saxony reviewed SF 1.10 AP Blanket and Fluid Warmer policy to ensure it appropriately identified the required standards of practice. On or before March 2, 2014, Saxony EVS staff was reeducated regarding the SF 1.10 AP policy with special emphasis on cleaning the exterior and interior of all blanket warmers on a monthly basis or when visibly soiled per policy. Monitoring: Beginning in March, periodic random observations will take place to ensure appropriate procedures are followed and the exterior and interior of blanket warmers are clean, i.e. without dust. Any identified gaps will immediately be discussed with the appropriate EVS staff member on an individual basis for performance improvement. Additionally, blanket warmer cleaning logs will be reviewed for completion and maintained. Responsible Person: Saxony Program Manager for Quality, Risk, and Compliance</p> |   |  |   |  |

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|                    | <p>accreditation/regulatory specialist), it was observed at 12:22 PM outside room #2: a large amount of accumulated dust under the plenum (lower shelf) of the top cabinet of the MEC blanket warmer</p> <p>5. interview with staff members #66 and #73 at 12:25 PM on 1/27/14 indicated confirmation of an extreme amount of dust seen in the cath lab blanket warmer</p> <p>6. review of the Aramark PM (preventive maintenance) document for the blanket warmer numbered 500572 indicated:</p> <p>a. the PM was done on 1/28/14 (the day after observation by the surveyor)</p> <p>b. there is no documentation, within the preventive maintenance actions listed, that indicate any cleaning of the interior of the warmer was included</p> <p>7. interview on 1/29/14 at 1:55 PM with staff member #78, the interim director of EVS, indicated:</p> <p>a. the blanket warmer policy indicates monthly cleaning will be accomplished</p> <p>b. contracted housekeeping staff should service/maintain the blanket warmers at the Saxony hospital off site</p> <p>c. there is no oversight of the contracted EVS employees by this staff member (or their staff)</p> |               |   |                      |

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| S001128            | <p>d. there is no documentation of monthly internal cleaning of blanket warmers by EVS staff, either for off site facilities, or for those supervised by this staff member</p> <p>410 IAC 15-1.5-8<br/>PHYSICAL PLANT<br/>410 IAC 15-1.5-8(c)(1)</p> <p>(c) In new construction, renovations, and additions, the hospital site and facilities, or nonlicensed facilities acquired for the purpose of providing hospital services, shall meet the following:</p> <p>(1) The 2001 edition of the national "Guideline for Construction and Equipment of Hospitals and Medical Facilities" (Guidelines).<br/>Based on observation and document review, the facility failed to follow the 2001 edition of the national " Guidelines for Construction and Equipment of Hospital and Medical Facilities" in 2 instances.</p> <p>Findings:</p> <p>1. On 1-28-14 at 10:10 am, in the presence of employee #A23, it was observed in the dirty linen processing area of Methodist Hospital there was no handwashing sink.</p> <p>2. On 1-28-14 at 10:15 am, in the</p> | S001128       | <p>Tag S 1128 Rule 410 IAC 15-1.5-8 Findings: failed to install a handwashing sink in the clean linen processing area and the dirty linen processing area. Corrective Action (s): The Methodist Hospital Facilities team has reviewed and approved a plan for installation of handwashing sinks in MH dirty and clean linen processing areas and estimates for work were secured. An estimate for the work was provided by Leach &amp; Russell Mechanical on February 28, 2014. The sinks should be installed by April 1, 2014. Responsible Person: Hospital Maintenance Administrator</p> | 04/01/2014           |

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| S001150            | <p>presence of employee #A23, it was observed in the clean linen processing area of Methodist Hospital there was no handwashing sink.</p> <p>3. Review of the 2001 edition of the national " Guidelines for Construction and Equipment of Hospital and Medical Facilities " , section 7.23.D4. indicates [there is to be] employee handwashing stations in each room where clean or soiled linen is processed and handled.</p> <p>410 IAC 15-1.5-8<br/>PHYSICAL PLANT<br/>410 IAC 15-1.5-8 (c)(9)</p> <p>(c) In new construction, renovations and additions, the hospital site and facilities, or nonlicensed facilities acquired for the purpose of providing hospital services, shall meet the following:</p> <p>(9) All back flow prevention devices shall be installed as required by 327 IAC 8-10 and the current edition of the Indiana plumbing code. Such devices shall be listed as approved by the department.</p> <p>Based on observation, the hospital failed to install backflow prevention devices as required by 327 IAC 8-10 and the current addition of the Indiana plumbing code in 2 instances.</p> | S001150       | Tag S 1150 Rule 410 IAC 15-1.5-8 Findings: the hospital failed to install a backflow prevention device in a patient bathroom shower at the offsite Sleep Center and in the equipment clean room at the offsite Sleep Center. Corrective | 02/28/2014           |

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|                    | <p>Findings:</p> <ol style="list-style-type: none"> <li>On 1-28-14 at 2:55 pm in the presence of employee #A5, it was observed in a patient bathroom shower at the offsite Sleep Center, there was a flexible hose connected to a water spigot without a backflow prevention device.</li> <li>On 1-28-14 at 3:00 pm in the presence of employee #A5, it was observed in the equipment clean room at the offsite Sleep Center, there was a flexible hose connected to a water spigot without a backflow prevention device.</li> </ol> |               | <p>Action(s): On February 28, 2014, estimates for installation of both back flow prevention devices were provided by Leach &amp; Russell Mechanical and the work will be completed by March 21, 2014. Responsible Person: Hospital Maintenance Administrator</p> |                      |

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| S001172   | <p>410 IAC 15-1.5-8<br/>PHYSICAL PLANT<br/>410 IAC 15-1.5-8(e)(1)(A)(B)(C)</p> <p>(e) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, shall be kept clean and orderly in accordance with current standards of practice as follows:</p> <p>(1) Environmental services shall be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:</p> <p>(A) Asepsis<br/>(B) Cross-infection; and<br/>(C) Safe practice.</p> <p>Based on observation, interview and document review, the facility failed to maintain floors and walls in a clean and orderly manner in one of one sterile operating suite janitorial closet and failed to ensure cleanliness that guards against disease transmission using aseptic techniques and safe cleaning practices in both hospitals and off site locations toured.</p> <p>Findings include:</p> <p>1. On 1/28/14 at 10:00 am, during the tour of the operating suites of University Hospital, it was noted the janitor closet on the unit had dirty floors and walls</p> | S001172   | <p>Tag S1172 Rule: 410 IAC 15-1.5-8 (e) (1) (A) (B) (C)<br/>Findings: RH OR suite #3 top of anesthesia machine was dusty, air duct was also dusty.<br/>Corrective Action (s): On or before February 3, 2014, Riley Anesthesia support staff cleaned all anesthesia machines. Additionally, a cleaning schedule was created and cleaning of these machines is the responsibility of and signed off by the staff member closing the operating room at the end of each day.<br/>Monitoring: Beginning March 2014, these areas will be monitored on an ongoing basis during EVS rounding to ensure the deficiency has been corrected and will not recur. Responsible</p> | 02/03/2014  |  |   |  |

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|                    | <p>and there was an accumulation of dust and paper on the floor.</p> <p>2. Interview with OR Manager L#1 indicated the janitor closet should be clean.</p> <p>3. Review of hospital policy entitled, Environmental Cleaning in the Intra-Operative Perioperative setting, indicated on page 3 in section " V. Policy Statements ", in item "B. Equipment and fixtures requiring environmental cleaning and disinfection include, but are not limited to: #3, All furniture, including wheels, and casters, fixed and ceiling mounted equipment, surgical lights and external tracks, kick buckets, plasma and monitor screens, ventilation face plates, trash and linen receptacles, and cleaning equipment."</p> <p>4. review of the policy and procedure "Environmental Cleaning In The Intra-Operative Perioperative Setting", policy number 1.14 (POS), with an approval and effective date of May 2013, indicated:</p> <p>a. on page 3 under "V. Policy Statements", it reads: "...3. All furniture, including wheels, and casters, fixed and ceiling mounted equipment, surgical lights and external tracks, kick buckets, plasma and monitor screens, ventilation face plates, trash and linen</p> |               | <p>Person: Clinical Director of Perioperative Services Findings: UH OR janitor closet had dirty floors, walls, and dust and paper on the floor. Corrective Action (s): On or before January 31, 2014, the UH OR closet was cleaned including floors, walls and removal of dust and paper from floor. Monitoring: Beginning March 2014, these areas will be monitored on an ongoing basis during EVS rounding to ensure the deficiency has been corrected and will not recur. Responsible Person: Director of Environmental Services</p> |                      |

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|   | <p>receptacles, and cleaning equipment..."</p> <p>b. on page 5 under "VI. Procedures", section "F. Terminal Cleaning", it reads in item 8., "Walls and vents are to be cleaned in each suite monthly per environmental services, unit PSA (patient service assistants/associates), or by a contracted vendor."</p> <p>5. at 12:24 PM on 1/27/14, while on tour of the Saxony cath lab procedure room #2, in the company of staff member #66, an accreditation/regulatory staff member, #70, the facility quality/risk/infection person, and #73, a cath lab staff person, it was observed that:</p> <p>a. two wall air ducts had accumulated dust on the slats</p> <p>b. the top of the large ceiling mounted monitor had an accumulation of dust present</p> <p>6. at 3:10 PM on 1/27/14, while on tour of the Saxony hospital ED (emergency department) in the company of staff person #70, the facility quality/risk/infection person, and an ED registered nurse, staff member #79, it was observed in the trauma room that the wall air duct (back of the room) had accumulated dust present on the slats</p> <p>7. interview with staff member #70 at</p> |   |   |   |  |   |  |

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|   | <p>3:10 PM on 1/27/14 indicated:</p> <ul style="list-style-type: none"> <li>a. both the cath lab procedure room and the ED trauma room had dusty areas that should not have been present on air vents/ducts and equipment</li> <li>b. contracted EVS (environmental services) staff are responsible for cleaning the facility</li> </ul> <p>8. at 10:00 AM on 1/28/14, while touring the off site Cancer Center East in the company of staff members #71, an accreditation/regulatory staff member, and #75, the center manager, it was observed in the CT (computed tomography) room that:</p> <ul style="list-style-type: none"> <li>a. there was an accumulation of dust on the top of the contrast injector arm (ceiling mounted)</li> <li>b. there was an accumulation of dust on the top of the AED (automated external defibrillator) box/cabinet</li> </ul> <p>9. at 10:15 AM on 1/28/14, while touring the off site Cancer Center East in the company of staff member #71, an accreditation/regulatory staff member, and #75, the center manager, it was observed in the decontamination/biological room that the ceiling air vent had a large accumulation of dust present</p> <p>10. at 10:00 AM and 10:15 AM on</p> |   |   |   |  |   |  |

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|                    | <p>1/28/14, interview with staff members #71, and #75 agreed that the items mentioned in 7. and 8. above were not cleaned as would be expected by the contracted cleaning company</p> <p>11. at 1:55 PM on 1/28/14, while on tour of the Riley hospital surgery areas in the company of staff members #80, the RN (registered nurse)/surgery director, and #81, the RN director/manager of the NICU (neo-natal intensive care unit) at the facility and tour guide, it was observed in suite #3 that:</p> <ul style="list-style-type: none"> <li>a. the top of the anesthesia machine was dusty</li> <li>b. the air duct on the back wall was dusty on the slats of the duct/vent</li> </ul> <p>12. at 1:55 PM on 1/29/14, interview with staff members #70, the quality/risk/infection staff member at Saxony, #78, the interim director of EVS (environmental services), #82, the facility/health system interim infection preventionist, and #83, the infection preventionist for off site facilities, indicated:</p> <ul style="list-style-type: none"> <li>a. the quality/infection staff member at Saxony should be monitoring the contracted cleaning staff at that facility</li> <li>b. currently, staff member #83 is not orienting, observing, supervising,</li> </ul> |               |   |                      |

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| S001216   | <p>checking competencies, or in any way monitoring the contracted cleaning agencies at the off site locations</p> <p>c. per staff member #78, EVS staff are to be monitored by their supervisors related to their cleaning performance and competency in the OR suites</p> <p>410 IAC 15-1.5-9<br/>RADIOLOGIC SERVICES<br/>410 IAC 15-1.5-9(b)(1)(A)(B)(i)(ii)(iii)(iv)(v)(C)</p> <p>(b) The services that use ionizing radiation shall not compromise the health, safety, and welfare of patients or personnel in accordance with federal and state rules, as follows:</p> <p>(1) Proper safety precautions shall be maintained against radiation hazards in accordance with the hospital's radiation and safety program as developed by the radiation safety officer. This includes, but is not limited to, the following:</p> <p>(A) Adequate shielding for patients, personnel, and facilities.<br/>(B) Procedures for monitoring:<br/>(i) skin dosage;<br/>(ii) radionuclide contamination;<br/>(iii) quality control;<br/>(iv) technique charts, where applicable; and<br/>(v) handling of hazardous materials.<br/>(C) Appropriate storage, use, and disposal of radioactive materials.<br/>Based on interview and document</p> | S001216   | Tag S 1216 Rule 410 IAC   | 03/02/2014  |  |   |  |

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|   | <p>review, the hospital failed to follow its policy for proper storage of radiation dosage badges in 1 instance.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>In interview, on 1-28-14 at 1:10 pm, interview of a staff radiology tech in the Rehab/CT area of the Neuroscience Building at Methodist Hospital indicated some staff took their dosimeter monitoring badges home at the end of their workday.</li> <li>Review of Radiology Policy#: 8.4.04, entitled RADIATION SAFETY: PERSONNEL MONITORING, effective October 2012, indicated personnel monitoring badges should not be taken home.</li> </ol> |   | <p>15-1.5-9Findings: MH Neuroscience Bldg Hospital Rehab/CT AreaHospital failed to follow its policy for proper storage of radiation dose badges. Corrective action(s): On or before March 2, 2014, MH Radiology reviewed and revised 8.4.04 Radiation Safety: Personnel Monitoring policy to ensure it appropriately identified the required standards of practice. The revisions include removing the provision that indicated that staff were prohibited from taking their radiation dose badges home this will bring current practice into compliance with policy expectations. After consideration that many techs report to multiple locations frequently they need to have the ability to take their badges home at the end of their shift. This will ensure the badge will detect the staff members cumulative dose on an ongoing basis. Responsible Person: Radiology Quality Assurance Coordinator</p> |                      |   |