

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  150058	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  01/17/2013
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NAME OF PROVIDER OR SUPPLIER  MEMORIAL HOSPITAL OF SOUTH BEND	STREET ADDRESS, CITY, STATE, ZIP CODE 615 N MICHIGAN ST SOUTH BEND, IN 46601
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S0000	<p>This visit was for a standard licensure survey.</p> <p>Facility Number: 005053</p> <p>Survey Date: 1/ 14-17/2013</p> <p>Surveyors: ReBecca Lair, LCSW Medical Surveyor</p> <p>Jacqueline Brown, RN Public Health Nurse Surveyor</p> <p>Lynnette Smith, Medical Surveyor</p> <p>Albert Daeger Medical Surveyor</p> <p>Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 01/29/13</p>	S0000	<p>A summary dashboard containing a list of all deficiencies found durring the survey, corrective actions, ongoing compliance actions and results of audits/monitoring has been created. The dashboard will be used to communicate the effectiveness of the corrective actions to Hospital Leadership on a monthly basis. In addition, a summary of the survey results, corrective actions and audit/monitoring results will be presented to the Hospital and System Boards of Directors on a quarterly basis.</p>	

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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S0102	<p>410 IAC 15-1.2-1 COMPLIANCE WITH RULES 410 IAC 15-1.2-1 (a)</p> <p>(a) All hospitals shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.</p> <p>Based on personnel file review and interview, the facility failed to comply with all applicable state laws for 5 of 5 unlicensed patient care personnel files reviewed (#P6, P7, P8, P9, and P10).</p> <p>Findings included:</p> <p>1. Review of state IC 16-28-13-4 indicated a health care facility shall apply within three (3) business days from the date a person is employed as a nurse aide or other unlicensed employee for a copy of the person's state nurse aide registry report from the state department and a limited criminal history from the Indiana central repository for criminal information under IC 5-2-5 or another source allowed by law.</p> <p>2. Review of personnel files on 01/15/13 with staff member #A6 indicated the following:</p> <p>A. The file for staff member #P6, hired 06/14/11 as a patient care assistant, lacked documentation of a Nurse Aide Registry report.</p>	S0102	<p>The Director of Human Resources holds responsibility for corrective actions and ongoing compliance. Patient Care Assistant, Unit Assistant, Nurses Aide, Mental Health Tech, Unit Clerk and Clinical Associates who are hired or transfer into one of these jobs will have their name put through the <a href="https://secure.in.gov/apps/pla/search.htm?pymt=1">https://secure.in.gov/apps/pla/search.htm?pymt=1</a> web site. Staff members #P6, #P7, #P8, #P9, #P10 were entered in the web site and no pending issues were found. A NA questionair has been created to assist with using this site. The job descriptions for the above positions do not require CNA certification. Calls were placed to Darleen Jones and Ann Hamel with the State Board of Health to clarify/confirm our process meets the state requirements. The Director of Talent Management will conduct a monthly audit of 5 new hire or transfer files to monitor ongoing compliance. The audit results will be reported to the Director fo Human Resources. Compliance will be reported to Hospital Leadership and the Chief Human Resources Officer of Beacon</p>	02/12/2013	

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	<p>B. The file for staff member #P7, hired 12/04/11 as a patient care assistant, lacked documentation of a Nurse Aide Registry report.</p> <p>C. The file for staff member #P8, hired 01/12/09 as a patient care assistant, lacked documentation of a Nurse Aide Registry report.</p> <p>D. The file for staff member #P9, hired 05/09/11 as a patient care assistant, lacked documentation of a Nurse Aide Registry report.</p> <p>E. The file for staff member #P10, hired 10/09/08 as a unit assistant, lacked documentation of a Nurse Aide Registry report.</p> <p>3. At 12:50 PM on 01/15/13, staff member #A6 confirmed the nurse aide registry check was not done and indicated he/she was unaware of this requirement.</p>		Health System on a monthly basis and quarterly to the Hospital and System Boards of Directors..	

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S0308	<p>410 IAC 15-1.4-1 GOVERNING BOARD 15-1.4-2 (c)(6)(B)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive officer develops policies and programs for the following:</p> <p>(B) Orientation of all new employees, including contract and agency personnel, to applicable hospital, department, service, and personnel policies.</p> <p>Based on review of personnel files and interview, the governing board failed to ensure all employees received departmental orientation in 2 of 4 CST (certified surgical techs) files reviewed (#P11 and P13) and departmental and hospital orientation in 4 of 4 agency staff (#P15, P16, P17, and P18) files reviewed.</p> <p>Findings included:</p> <p>1. Review of personnel files on 01/15/13 with staff member #A6 indicated the following: A. The file for CST staff member #P11, hired 09/14/09, lacked documentation of departmental orientation. B. The file for CST staff member #P13, hired 09/07/04, indicated an incomplete departmental orientation form.</p>	S0308	The Director of Human Resources is responsible for corrective actions and prevention of reoccurrence for all deficiencies related to Tag 0308.CST staff members #P11 and #P13 will receive departmental orientation and appropriate documentation of such will be placed in their employee files no later than 2/28/13. The Surgery Department will utilize a department orientation plan checklist for all new hires to document completion of each element included in the plan. Human Resources will conduct a quarterly audit of department employee files on 5% of new hires to monitor ongoing compliance. The Director of Human Resources will report non-compliance to the Executive Director of Surgical	02/28/2013			

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	<p>C. The file for agency staff member #P15, an RN (registered nurse) with a start date of 12/26/12, lacked documentation of departmental or hospital orientation.</p> <p>D. The file for agency staff member #P16, a CNA (certified nursing assistant) with a start date of 10/05/12, lacked documentation of departmental or hospital orientation.</p> <p>E. The file for agency staff member #P17, an RN with a start date of 08/21/12, lacked documentation of departmental or hospital orientation.</p> <p>F. The file for agency staff member #P18, a CNA with a start date of 11/02/12, lacked documentation of departmental or hospital orientation.</p> <p>2. At 11:05 AM on 01/17/13, staff member #A6 confirmed the findings, but indicated the agency staff members had not actually worked the floors yet. He/she acknowledged their files indicated they were ready to work and should have been oriented before they were actually needed on the units.</p>		<p>Services. Agency and contract staff will receive general hospital and department orientation and be required to take a quiz prior to being able to start work. General and department orientation has been added to the checklist which is used by Human Resources staff when adding an agency or contract person to the list of approved agency staff. The Director of Human Resources will conduct a quarterly audit on 5% of approved agency staff files to monitor ongoing compliance. Compliance data for both deficiencies will be reported to Hospital Leadership and the Chief Human Resources Officer of Beacon Health System on a monthly basis and quarterly to the Hospital and System Boards of Directors.</p>		

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S0322	<p>410 IAC 15-1.4-1 GOVERNING BOARD 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: (6) Require that the chief executive officer develops policies and programs for the following:</p> <p>(H) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based on observation, facility documentation, manufacturer's literature, and interview, the governing board failed to ensure policies and procedures were in place to ensure patient safety with the use of heated supplies.</p> <p>Findings included:</p> <p>1. During the tour of the Emergency Department at 9:30 AM on 01/16/13, accompanied by staff members #A5, A11, and A12, a Skytron warmer was observed registering 109 degrees Fahrenheit (F) with a label indicating the range was 104-114. The warmer contained 14 bags of intravenous (IV) fluid and 2 bottles of irrigation fluid along with blankets. The temperature was recorded daily on "Peds crash cart/Critical Care Checklist" form and ranged from 109 to 113 degrees for</p>	S0322	The Chief Nursing Officer is responsible for corrective and preventative actions related to deficiencies identified under Tag 0322. The policy 'Warming Fluids' was reviewed and revised on 2/12/13 to establish the maximum fluid warmer cabinet temperature of 104 degrees F in accordance with AORN (Association of PeriOperative Registered Nurses) recommendations and various fluid manufacturer guidelines. In addition, temperature monitoring requirements were changed from weekly to daily. The associated temperature monitoring log form was updated accordingly. The temperature log sheets will be reviewed by Surgical Services Administration on a weekly basis. A new policy 'Blanket Warmers' was created on 2/08/13 to establish a process for appropriate use of warmed blankets, a maximum warmer	02/16/2013	

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	<p>November and December 2012.</p> <p>2. During the tour of the operating areas of the obstetrical unit at 10:45 AM on 01/16/13, accompanied by staff members #A10, A13, and A14, a Steris warmer was observed registering 125 degrees F. The warmer contained 10 bags of IV fluid and 7 bottles of irrigation fluid along with blankets. The label on the warmer indicated fluids should be 115 degrees and blankets should be 150 degrees. Staff member #A13 indicated there was no temperature monitoring logs for the unit.</p> <p>3. During the tour of the nursery at 11:10 AM on 01/16/13, accompanied by staff members #A10 and A16, a warmer, containing blankets only, was observed registering 120 degrees F. Staff member #A16 indicated the temperature was not monitored and was recommended by plant operations.</p> <p>4. During the tour of the Orthopedic unit at 2:45 PM on 01/16/13, accompanied by staff members #A10, A19, and A20, a Steris warmer, containing blankets, was observed registering 149 degrees F. Staff member #A19 indicated he/she "eyeballed" it and there was no temperature monitoring log.</p> <p>5. During the tour of the 7 intermediate</p>		<p>cabinet temperature of 130 degrees F , and daily cabinet temperature monitoring. In addition, labels will be placed on all blanket warmer cabinets which state "DO NOT USE IF TEMPERATURE IS &gt;130 DEGREES F". The safe temperature of 130 degrees F is based on recommendations from ECRI Institute and AORN (Association of PeriOperative Registered Nurses). Daily temperature log forms will be faxed to the Safety Coordinator on a weekly basis. Safety Coordinator will determine rate of compliance and report rate and non-compliant departments to Nursing Leadership weekly. Compliance data will be reported to Hospital Leadership on a monthly basis and quarterly to the Hospital and System Boards of Directors.</p>				

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	<p>unit at 3:10 PM on 01/16/13, accompanied by staff members #A10, A21, A22, and A23, a Steris warmer, containing blankets, was observed registering 145 degrees F. Staff member #A21 indicated the temperature was recommended by engineering and there was no temperature monitoring log.</p> <p>6. During the tour of 12 South at 10:15 AM on 01/17/13, accompanied by staff members #A10, A25, and A26, a Steris warmer, containing blankets, was observed registering 162 degrees F. Staff member #A25 indicated he/she "eyeballed" it and there was no temperature monitoring log.</p> <p>7. During the tour of 11 South at 10:35 AM on 01/17/13, accompanied by staff members #A10, A25, and A26, a small Amsco warmer, containing blankets, was observed with no temperature registering device. The dial was set above "high", but the temperature could not be determined. Staff member #A25 indicated there was no temperature monitoring log.</p> <p>8. The facility policy "Warming Fluids", effective 09/16/09, indicated, "A. Temperature parameters: 1. Intravenous fluids in plastic bag with overwrap intact: a. Warm to a maximum of 115 degrees F.</p>						

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	<p>2. Pour solution in plastic containers: a. Warm to a maximum of 150 degrees F. ...F. Temperatures will be monitored on a weekly basis and recorded on the Fluid Warmer Temperature Quality form."</p> <p>9. Literature from Baxter Health Care Corporation, the manufacturer of the fluids used in the facility, indicated IV bags in plastic over-pouches may be warmed for no longer than 14 days at a temperature not to exceed 104 degrees F. and irrigating solutions for 72 hours at 150 degrees F.</p> <p>10. At 4:10 PM on 01/16/13, staff member #A5 indicated the facility had no policy for the blanket warmers and indicated the fluid policy was out of date. He/she also indicated he/she was unsure of where the temperatures listed in the fluid policy were obtained since they were not the ones recommended by the manufacturer.</p>			

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S0330	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(c)(6)(K)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive officer develops policies and programs for the following:</p> <p>(K) Maintaining personnel records for each employee of the hospital which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-ray, as applicable.</p> <p>Based on review of job descriptions, personnel records, policies and procedures, manufacturer's literature and staff interview, the hospital failed to maintain education records, as required by their job description, for 2 of 2 medical laboratory technician records reviewed and failed to ensure TB testing/screening was performed according to policy for 6 of 18 staff members (#P2, P9, P11, P13, P17, and P18).</p> <p>Findings included:</p> <p>1. Review of job descriptions on 1-16-13 between 11:00 AM and 1:00 PM</p>	S0330	The Job description for Laboratory Technician was reviewed and revised on 2/12/13 in accordance with CLIA guidelines found under CFR 493.1489 and CFR 493.1423 to ensure employees meet education requirement to work in the lab. An audit of all Lab employee files was completed on 2/08/13 to ensure staff meet CLIA requirements. It was determined that staff member #L1 met the educational requirement as evidenced by Health Education Welfare Certification and educational transcript provided on 2/11/13. Staff member #L2's employment with the organization terminated on 1/31/13, therefore	03/01/2013

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	<p>indicated a job description titled: "Medical Laboratory Technician", job code "12242", which read: "Knowledge, Skills, and Abilities...The above level of knowledge, skills, and abilities is acquired through the successful completion of an Associate's degree in Clinical Laboratory Sciences, successful completion of an approved clinical laboratory internship..." Information supplied to the hospital from "Background Information Services, Inc."</p> <p>2. Review of personnel records on 1-16-13 between 11:00 AM and 1:00 PM indicated the following:</p> <p>a. Staff Member #L1 was a "Medical Laboratory Technician." Information supplied to the hospital from "Background Information Services, Inc." indicated the staff member did not have an associate's degree, as required by the job description., and there was no documentation to indicate the staff member had completed an "approved clinical laboratory internship."</p> <p>b. Staff Member #L2 was a "Medical Laboratory Technician." There was no documentation to indicate the staff member had completed an "approved clinical laboratory internship," as required by the job description.</p> <p>3. In interview on 1-16-13 between 3:50</p>		<p>educational documentation was not obtained. Ongoing compliance will be maintained utilizing existing applicant screening process.Beginning 3/01/13, QFT Gold serology testing will be implemented as the primary means for screening associates upon hire and post exposure. TST will remain a secondary means of screening should QFT Gold serology testing not be feasible. Should TST be indicated, it will be completed upon hire with a interval time frame of 1-3 weeks between first and second TST. TST will be documented with the date and time of administration and reading. The Tuberculosis policy and procedure will be amended on 3/01/13 to reflect these changes. Manager of Employee Health will conduct monthly audits on 100% of new hires. Audit results will be reported to the Director of Benefits &amp; Compensation.Compliance data will be reported to Hospital Leadership and the Chief Human Resources Officer of Beacon Health System on a monthly basis and quarterly to the Hospital and System Boards of Directors.</p>				

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	<p>PM and 4:00 PM, Staff Members #L6 and L10 acknowledged the above findings.</p> <p>4. Review of personnel files at 12:15 PM on 01/15/13 with staff member #A6 indicated the following:</p> <p>A. The file for staff member #P2, hired 08/09/11, indicated a first step TB test done on 07/19/11 and read on 07/22/11 and the second step test done on 07/22/11 and read on 07/25/11.</p> <p>B. The file for staff member #P9, hired 05/09/11, indicated a first step TB test done on 05/05/11 and read on 05/07/11 and the second step test done on 05/09/11 and read on 05/11/11.</p> <p>C. The file for staff member #P11, hired 09/14/09, indicated the last TB test was placed on 05/07/12, but no time was documented, and was read at 1245 on 05/09/12, but it was unable to be determined whether the reading was 48 to 72 hours after the placement.</p> <p>D. The file for staff member #P13, hired 09/07/04, indicated the last TB test was placed at 1045 on 10/08/08 and read at 0730 on 10/10, less than 48 hours later.</p> <p>E. The files for 2 agency staff members, #P17 and P18, lacked documentation of the second step TB test required upon hire.</p> <p>5. Review of the facility policy "Tuberculosis Screening for [facility] Team Members", effective 05/01/2009,</p>						

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	<p>indicated, "[Facility] will follow ISDH and CDC recommendations related to screening Team Members. ...Screening at Hire: A 2 step TB test or serology testing and a TB questionnaire as outlined in the Post Offer Physical policy is mandatory." CDC recommendations were to perform a 2 step TB test upon hire, the second test placed 1 to 3 weeks after the first, and each test read 48 to 72 hours after placement.</p> <p>6. The manufacturer's literature for Aplisol, the solution used for the TB testing, indicated, "Booster Effect and Two-Step Testing: ...In this testing method, persons who have a negative initial skin test undergo a second tuberculin skin test 1- 3 weeks after the first. Both tests should be read and recorded at 48 to 72 hours."</p> <p>7. At 2:30 PM on 01/15/13, the employee health nurse, staff member #A7, explained a situation arose because of a 15 minute delay in reading a TB test so the facility indicated in their policy that the TB test should be read in 2- 3 days, rather than 48- 72 hours. He/she also indicated that it was acceptable to give the second step TB test as soon as the first step was read. He/she acknowledged the facility followed CDC guidelines.</p>			

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	8. At 11:05 AM on 01/17/13, staff member #A6 confirmed the findings and acknowledged the TB tests were not performed or read according to CDC and manufacturer's guidelines.			

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S0362	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(d)(6)(A)(B)(C)(D) (E)(F)</p> <p>(d) The governing board is responsible for assuring that quality patient care is provided. In accordance with hospital policy, the governing board shall do the following:</p> <p>6) Ensure that the hospital does the following:</p> <p>(A) Establish written protocols to identify potential organ and tissue donors. (B) Has written policies and procedures for the facilitation of organ and tissue donations, including procurement. (C) Inform families or authorized persons of potential organ and tissue donors of the option of donation on admission or at the time of death of a potential donor. (D) Use discretion and sensitivity in contacts with potential organ donor families. (E) Notify the appropriate procurement organization of potential organ donors. (F) Establish membership in the organ procurement and transplantation network if the hospital performs transplants.</p> <p>Based on document review and employee interview, the facility failed to notify the appropriate organ procurement organization, per contract, of all hospital deaths.</p>	S0362	The Executive Director of Surgical Services is responsible for corrective and preventative actions. The variance was discovered on October 17, 2012 during the monthly review	02/08/2013

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	<p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the contract between the hospital and the Indiana Organ Procurement Organization (IOPO) indicated the hospital shall provide "Timely Referral to IOPO as soon as possible of every individual whose death is imminent or who has died in the hospital".</li> <li>2. Review of Donation 2012 Statistics and Benchmarks indicated 39 deaths occurred in September 2012 and only 38 deaths were reported.</li> <li>3. Interview with Employee #A4 and review of the IOPO contract documentation on January 15, 2013 at 1:30pm, verified the information.</li> </ol>		<p>meeting between Memorial donation team, IOPO, and Indiana Lions Eye and Tissue Transport Bank representatives. An investigation of the variance at that time determined the patient's medical record contained documentation of early referral to IOPO while the patient was at Riley Hospital prior to being transferred to Memorial. The nurse was not aware of the additional need to call the Donation Information Line at time of cardiac death. Staff were re-education on the process on 10/26/12 to prevent reoccurrence in the future. The Donation PI Team meets with representatives from IOPO and Indiana Lions Eye and Tissue Transplant Bank monthly to review deaths &amp; referrals. Any variance identified at the monthly review meeting will be reported to the Executive Director of Surgical Services. Ongoing compliance will be reported monthly to Hospital Leadership and quarterly to the Hospital and System Boards of Directors.</p>		

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S0392	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(f)(2)</p> <p>(f) The governing board is responsible for services delivered in the hospital whether or not they are delivered under contracts. The governing board shall insure the following:</p> <p>(2) That the services performed under a contract are provided in a safe and effective manner and are included in the hospital's quality assessment and improvement program.</p> <p>Based on document review and staff interview, the governing board failed to assure that the services performed under a contract were provided in a safe and effective manner and were included in the hospital's quality assessment and improvement program (QAPI) for 5 (Housekeeping, Dietary Services, Laundry Services, Renal Dialysis and Pet Therapy Services) of 11 contracted services.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Review of the hospital's QAPI program indicated lack of quality monitor indicators and standards for five contracted services: Housekeeping, Dietary Services, Laundry Services, Renal Dialysis and Pet Therapy Services.</li> <li>Interview with Employee #A3,</li> </ol>	S0392	The Director of Risk Management is responsible for corrective and preventative actions. The policy 'Contracts and Other Legal Agreements' was revised on 2/11/13 to require the Directors agree on quality indicators with the contracted service that meet a minimum threshold to assure safe and effective delivery of services provided. In addition, the standard contract templates were revised on 2/11/13 to include appropriate language in regard to quality and performance indicator requirements. Compliance will be monitored by requiring quarterly reporting of quality indicators for all contracted services to the Hospital Board Quality Committee. The hospital no longer has an agreement for PET Scan services as a result of the recent purchase of the necessary equipment to perform these services. The PET Scan service was removed from the	02/11/2013			

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	<p>Employee #4, and #A9 on January 15, 2013 at 3pm verified these findings.</p> <p>3. Interview with Employee #A4 on January 17, 2013 at 9:45am indicated "we do not track these contracted services nor report on up to the Board on these services".</p>		<p>organizations list of contracted services on 2/01/2013.</p>		

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S0406	<p>410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 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.</p> <p>Based on document review and staff interview, the governing board failed to assure that all services were included in the hospital's quality assessment and improvement program (QAPI) for 5 (Housekeeping, Dietary Services, Laundry Services, Renal Dialysis and Pet Therapy Services) of 11 contracted services.</p> <p>Findings:</p> <p>1. Review of the hospital's QAPI program indicated lack of quality monitor indicators and standards for five contracted services: Housekeeping, Dietary Services, Laundry Services, Renal Dialysis and Pet Therapy Services.</p> <p>2. Interview with Employee #A3,</p>	S0406	<p>The Vice President of Medical Staff Affairs, Quality &amp; Safety is responsible for corrective and preventative actions. The Quality Scorecard, which is presented to the Medical Executive Committee and the Hospital Board Quality Committee, will be revised by 2/16/13 to include quality metrics for all contracted services including Dietary, Laundry, Housekeeping and Renal Dialysis services. The hospital no longer has an agreement for PET Scan services as a result of the recent purchase of the necessary equipment to perform these services. The PET Scan service was removed from the organizations list of contracted services on 2/01/2013. The performance data will be reported monthly to the Medical Executive Committee and quarterly to the Hospital</p>	02/16/2013			

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	<p>Employee #4, and #A9 on January 15, 2013 at 3pm verified these findings.</p> <p>3. Interview with Employee #A4 on January 17, 2013 at 9:45am indicated "we do not track these contracted services nor report on up to the Board on these services".</p>		Board Quality Committee.	

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S0554	<p>410 IAC 15-1.5-2 INFECTION CONTROL 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 observation, policy and procedure review, document review, manufacturer's directions and personnel interview, the facility failed to provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors by failing to measure the enzymatic product and/or the water used to disinfect surgical instruments prior to sterilizing in 1 of 7 (Decontamination Area of Sterile Processing) areas toured and failed to ensure a safe environment for patients by checking supplies to prevent outdated usage.</p> <p>Findings:</p> <p>1. While on tour of facility on 1/16/13 at approximately 1:45 PM, in the company of P3 and P13, the following was observed in the Decontamination Area of Sterile Processing: personnel are not measuring the enzymatic product and/or the water used to disinfect surgical instruments prior to sterilizing in 3 of 3 decontamination sinks.</p>	S0554	<p>The Chief Nursing Officer holds responsibility over corrective and preventative actions. All expired supplies were removed and discarded at the time of survey. A new process was established on 2/12/13 whereby a label will be placed on all carts, cabinets and other satellite supply storage locations indicating the most recent expiration date of medications &amp; supplies. Unit Assistants will audit the supplies weekly and update label as appropriate. Unit Directors will conduct random audits to ensure compliance with process. Results of the random audits will be reported to the Chief Nursing Officer on a monthly basis. Compliance data will be reported to Hospital Leadership on a monthly basis and quarterly to the Hospital and System Boards of Directors.</p>	02/12/2013			

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	<p>2. Policy titled, "Reprocessing Instruments" with a reapproval date of 2/21/12, was reviewed on 1/16/13 at approximately 3:41 PM, and indicated on pg. 1, under Procedure section, points 1. and 5., "Instruments should be covered with water, the appropriate hospital approved enzyme disinfectant solution, and contained for transportation to the OR instrument room...Wash manually, using friction under water and appropriate hospital approved disinfection solution."</p> <p>3. Label titled, "Medical Enzyme Detergent", was reviewed on 1/16/13 at approximately 3:41 PM, and indicated, under Directions section, point 2., "Add 1/2 - 1 ounce of Mild Foaming Medical Enzyme Detergent per 1 gallon water."</p> <p>4. Personnel P13 was interviewed on 1/16/13 at approximately 2:00 PM and confirmed, the above-mentioned hospital approved disinfection solution was not being measured and the water was not being measured according to manufacturer's directions. This should be measured appropriately to disinfect surgical instruments prior to sterilizing.</p> <p>5. During the tour of the Emergency Department at 9:30 AM on 01/16/13, accompanied by staff members #A5, A11, and A12, the following expired items</p>			

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	<p>were observed in a cabinet in trauma room 27:</p> <p>A. One of one Shiley trach expired 09/2012.</p> <p>B. Two of two thoracentesis/paracentesis trays, one expired 05/2010 and one expired 03/2011.</p> <p>6. During the tour of the pediatric unit at 11:45 AM on 01/16/13, accompanied by staff members #A10, A17, and A18, the following expired items were observed in the respiratory box in the treatment room:</p> <p>A. Two of two Calcium Alginate tipped applicators expired 06/2010.</p> <p>B. One of one Yankauer suction expired 04/2006.</p> <p>7. During the tour of the pediatric ICU at 12:10 PM on 01/16/13, accompanied by staff members #A10, A17, and A18, the following expired items were observed in the sedation cart:</p> <p>A. One of two BD Insyte 20 gauge needles expired 12/2010.</p> <p>B. One of two BD Saf-T-intima 20 gauge expired 12/2011.</p> <p>8. During the tour of the 7 intermediate unit at 3:10 PM on 01/16/13, accompanied by staff members #A10 and A21, one of one arterial blood sampling kit with an expiration date of 07/2012 was observed on the cart in the charge nurse</p>			

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S0608	<p>410 IAC 15-1.5-2 INFECTION CONTROL 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: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (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 review of policies and procedures, observation and staff interview, the infection control committee failed to ensure adherence to hand hygiene policies for Emergency Department Laboratory and the Production Kitchen and failed to establish requirements for attire appropriate for the kitchen work setting.</p> <p>Findings included:</p> <p>1. Hand Hygiene Policy, last reviewed May 2010, states, "Wash hands with soap specific to your area and water when hands are visibly dirty or contaminated with proteinaceous material examples: blood, body fluid, etc."</p>	S0608	The Hospital Infection Preventionist holds responsibility for corrective actions and prevention of reoccurrence. The Hospital Infection Preventionist reviewed the 'Hand Hygiene' policy and determined the current practice of utilizing alcohol-based waterless antiseptic agent to be in accordance with the CDC Indications for Handwashing and Hand Antisepsis as stated in the CDC Morbidity and Mortality Weekly Report Vol. 51, /No RR-16 dated October 25, 2002, page 32 section G. The CDC recommendation states "Decontaminate hands after contact with body fluids or excretions, mucous membranes, non-intact skin, and wound dressings if hands are not visibly	02/08/2013			

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	<p>2. At 1:42 PM on 1/15/2013, the Emergency Department Laboratory was toured. Staff member A32 was observed sneezing in his/her hands. Then the staff member used hand sanitizer followed by putting on his/her gloves. The staff member then went to a patient's room to draw blood for the Laboratory. The staff member did not wash hands with soap and water as defined in the hospital's policy.</p> <p>3. Nutritional Services Personal Health and Hygiene policy, last reviewed May 2010, states, "Hands are to be washed before beginning work, after using the bathroom, after coughing, sneezing or blowing the nose, after touching hair, after leaving your work area, whenever changing tasks, after handling raw unwashed food and dirty dishes, before donning gloves and before touching food, clean dishes and silverware."</p> <p>4. The Production Kitchen was toured on 1/15/2012 at 10:30 AM. The kitchen staff throughout the Production Kitchen was observed not washing their hands as required. The lack of hand washing was evidenced by:</p> <p>a. One staff member was observed cleaning a meat slicer with</p>		<p>soiled". It was therefore determined that a revision to the policy was not warranted and the staff member observed utilizing hand sanitizer following a sneeze acted appropriately and according to policy and CDC recommendations. Ongoing compliance with the 'Hand Hygiene' policy will be monitored utilizing the existing process of direct observation and reporting results on the monthly patient safety monitoring tool. Compliance data is shared monthly with Hospital Leadership and the Nursing Quality &amp; Safety Council and quarterly with the Infection Control Committee. Education for Nutritional Services staff on the appropriate hand hygiene practice specific to food preparation and service was completed on 2/08/13 via email, staff meetings and department newsletter. The Nutritional Services department policy 'Personal Health and Hygiene' was revised on 2/08/13 to disallow staff from wearing wristwatches. In addition, language was added to the policy which states "beard guard may be required for staff and vendors at the discretion of management". All staff were educated on policy 2/08/13 via email and department newsletter. In addition, staff were required to read and sign the policy during staff meetings. Signs were posted on the entrance door utilized by</p>				

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	<p>sanitizing solution. Then the staff member was observed putting on single-use gloves then sliced turkey and caught the turkey slices with his/her right gloved hand. The staff member did not wash his/her hands between cleaning the meat slicer and putting on the gloves.</p> <p>b. One staff member was observed wiping down the patient deli cold counter bar with sanitizing solution while wearing single-use gloves. Then the staff member used his/her same wet gloved hand and handled a single serving pizza from the toaster oven and placed it on a patient's plate. The staff member did not wash hands between tasks and single-use gloves were not changed between tasks.</p> <p>c. Four staff members throughout the Production Kitchen were observed changing their single-use gloves multiple times without washing their hands between changing of the gloves.</p> <p>5. 410 IAC 7-24, section 134(a) reads:</p>		<p>Vendors on 2/08/13. Staff compliance with dress code and hand hygiene practice will be observed by department management on a daily basis. Non compliance issues will be corrected immediately, including progressive discipline if necessary. Compliance data will be reported to the Infection Preventionist and Hospital Leadership on a monthly basis and quarterly to the Infection Control Committee.</p>				

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	<p>"While preparing food, a food employee shall not wear jewelry, including medical jewelry and watches, on their arms and hands. This section does not apply to a plain ring, such as a wedding band." Section 138(b) reads: "food employees shall wear hair restraints, such as hats, hair coverings or nets, beard restraints..."</p> <p>6. Review of policies and procedures on 1-15-13 between 9:45 AM and 10:45 AM indicated a policy / procedure titled: "Department Dress Code", policy / procedure number "5.30", which read: "All employees will wear hair-covering restraints when in the preparation, service and dishwashing areas." and "Jewelry should be limited to wedding bands and wristwatches."</p> <p>7. During a tour of the main production kitchen on 1-15-13 between 10:45 AM and 3:30 PM, two food service employees preparing food on the patient tray line were observed wearing engagement rings, one food service employee preparing food on the patient tray line was observed wearing a watch, two food service workers walking between the patient tray line and the grill areas had beards and were observed without a beard restraint, and one vender with a beard was observed walking through the food preparation area to a food storage area without a beard</p>				

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	<p>restraint.</p> <p>8. In interview on 1-15-13 between 10:45 AM and 3:30 PM, Staff Member #L5 acknowledged the above findings.</p>			
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S0610	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(x)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (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>(x) A program of food preparation and storage for all personnel involved in food handling which includes, but is not limited to, the following:</p> <p>(AA) Storage of employee food in patient refrigerators.</p> <p>(BB) Medications in nutrition refrigerators.</p> <p>(CC) Refrigerator and freezer temperature monitoring.</p> <p>Based on policy review, observation and staff interview, the infection control committee failed to ensure refrigerators were being monitored for their temperatures as per hospital policy for the Morgue Risk Management Refrigerator, Sterile Core Area of Surgery and the Canteen stand-up storage refrigerators and failed to ensure the food program included storing potentially hazardous</p>	S0610	The Hospital Infection Preventionist is responsible for corrective actions and actions related to the prevention of reoccurrence. The refrigerators in the Morgue and the Sterile Core Area of Surgery were removed on 1/14/13. Temperatures in all other refrigerators located throughout the hospital which are utilized for the storage of patient medications or nutritional	02/08/2013

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	<p>food in accordance with 410 IAC 7-24 in 4 of 7 areas reviewed.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>1. Refrigerator Freezer Temperature Monitoring policy, last reviewed 10/18/2011, states, "Temperature Monitoring: Each non-alarm refrigerator-freezer unit used for patient products shall be monitored for proper temperature for storage. Routine quality control shall be the notation of this temperature on a temperature log sheet daily. Food Refrigerator / Freezer Log (#576207) shall be used for monitoring patient food and Breast Milk Refrigerators and/or freezers. Medication Refrigerator Log (form #576206) shall be used for monitoring medication and lab reagent refrigerators.</li> <li>2. At 2:30 PM on 1/15/2013, the Morgue was toured. The storage roof located off the Morgue was observed containing a small refrigerator labeled "Risk Management". The refrigerator was observed containing a plastic sack which was observed leaking fluid onto the refrigerator floor. The refrigerator was observed with a temperature log on it; however, the log was not filled out.</li> <li>3. At 10:00 AM on 1/16/2013, staff</li> </ol>		<p>products are monitored and documented daily. In locations that are not open 7 days a week, memory thermometers are utilized to ensure refrigerator temperatures remained in range while the department was closed. Log sheets are faxed weekly to the Safety Coordinator. The rate of compliance and non-compliance is reported weekly to Nursing Leadership and the Infection Preventionist. A new process was established on 2/08/13 with the Canteen vendor which requires the vendor to check and log refrigerator temperatures daily. If temperatures are outside of range at any time, Vendor will place refrigerator out of service and repair. The vendor will send the daily temperature log sheets to the Director of Nutritional Services on a weekly basis. Compliance data will be reported monthly to the Infection Preventionist and Hospital Leadership and quarterly to the Hospital and System Boards of Directors. All corrective actions were completed by 1/25/13 to address the appropriate storage of food in the main production kitchen. Corrective actions included placement of an ice bath beneath the cold storage well to improve cold holding, temperature adjustment to the CVAP "PM3721" food warmer for higher holding temperatures, temperature adjustment to the</p>				

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	<p>member A4 indicated he/she could not locate any temperature logs that the small storage refrigerator was being monitored for temperatures. The refrigerator was used for Risk Management.</p> <p>4. The Canteen food self-service convenient store was inspected at 2:15 PM on 1/15/2013. The Canteen had three stand-up sliding door refrigerators. None of the three had any temperature monitor records. The pre-made sandwiches stored in 1 of the three stand-up refrigerators were testing between 45 and 48 degree F. The three refrigerators ambient air temperatures were 40 F, 40 F and 45 F.</p> <p>5. At 11:40 AM on 1/17/2013, staff member A15 indicated the refrigerator temperatures were not being monitored by the vendor as required.</p> <p>6. At 1:31 PM on 1/16/2013, the Sterile Core Area of Surgery was toured. A refrigerator located in this areas was labeled "not be in use". However, the refrigerator was observed plugged in and was in operation. The product Evicel for tropical administration was observed stored within the refrigerator. The refrigerator was lacking a temperature log; therefore, the daily refrigerator temperatures were not being logged for this medication refrigerator.</p>		<p>pantry cooler #3 to allow for lower temperature, and the installation of an additional refrigerator to accommodate better holding temperatures. Equipment temperatures in the main kitchen area are monitored utilizing Smart Temps software. The Director of Nutritional Services is notified immediately via an automatically generated email when temperatures fall out of range. In addition, food temperatures are recorded by line servers during service and cooks during cooking process. If at any time a temperature is found to be out of range, a supervisor is notified to assess the situation and take appropriate action, including discarding of food and taking equipment out of service if necessary to resolve the situation. Nutritional Services Management staff will review food temperature logs twice daily and report non-compliance and/or trends to the Director of Nutritional Services. Equipment temperatures are monitored by Smart Temps software which provides for immediate/automatic notification when temps are out of range. Compliance data will be reported monthly to the Infection Preventionist and Hospital Leadership and quarterly to the Hospital and System Boards of Directors.</p>		

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	<p>7. 410 IAC 7-24, section 187(a) reads: "... potentially hazardous food shall be maintained as follows: (1) At one hundred thirty-five (135) degrees Fahrenheit or above... (2) At a temperature specified in the following: (A) At forty-one (41) degrees Fahrenheit or less."</p> <p>8. During a tour of the main production kitchen on 1-15-13 between 10:45 AM and 3:30 PM, while accompanied by Staff Members #L5 and #L8, the following potentially hazard food items were observed as follows:</p> <p>a. On the hot side of the patient tray line, in a cold storage well:</p> <p>1) Shredded parmesan cheese was maintained at 53 degrees Fahrenheit (F)</p> <p>2) shredded mozzarella cheese was maintained at 50 F</p> <p>3) Shredded cheddar cheese was maintained at 54 F</p> <p>4) Sliced American cheese was maintained at 54 F</p> <p>b. In the CVAP food warmer, number "PM3721", on the hot side of the patient tray line:</p> <p>1) Chicken was maintained at 124 F</p> <p>2) Meat loaf was maintained at 125 F</p> <p>c. On the hot food side of the patient tray line, in a cold food storage drawer</p>			

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	<p>under the salad preparation station:</p> <p>1) Chicken was maintained at 45 F</p> <p>2) Shredded mozzarella cheese was maintained at 49 F</p> <p>d. In the pantry cooler #3:</p> <p>1) Sliced eggs were maintained at 44 F</p> <p>2) Shredded cheddar cheese was maintained at 48 F</p> <p>3) Tuna salad was maintained at 45 F</p> <p>4) Chicken salad was maintained at 45 F</p> <p>9. In interview on 1-15-13 between 10:45 AM and 3:30 PM, Staff Members #L5 and #L8 acknowledged the above findings.</p>			

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S0612	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(xi)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (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>(xi) A program of linen management for personnel involved in linen handling. Based observation, document review, and staff interview, the facility failed to protect clean laundry and linen that were stored in the Morgue.</p> <p>Findings included:</p> <p>1. At 2:30 PM on 1/15/2013, the Morgue was inspected. At the rear of the Morgue located near the autopsy table was a counter with shelving units directly above the counter. On the counter were 5 stacks of folded clean linen stored on the counter. On the wall</p>	S0612	The Hospital Infection Preventionist is responsible for corrective actions. The Director of Environmental Services is responsible for preventative actions. All uncovered linen located on the counter and open shelving unit was removed and a new supply of clean linen was placed in a closed cabinet on 1/17/13. On 2/01/13 a team, including the Sr. Director of Operations, Lab Manager, House Float Director, Environmental Services Director, Facilities Director, and Infection Preventionist, was formed to establish a process, identify areas of responsibility, identify needed repairs and improvements to equipment and/or structure and to organize supplies & equipment in the morgue. The team met on	02/16/2013

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	<p>adjacent to the counter was a wall mounted 2 shelf open front shelving unit. On the shelves in the wall mounted shelving unit were 2 folded stacks of clean linen. The counter and the wall mounted storage unit was dusty to touch. The wall mounted storage cabinets located directly above the clean linen located on the counter was observed with heavy accumulation of dust and debris.</p> <p>2. At 3:30 PM on 1/15/2013, staff member A4 indicated the hospital does not have either a policy or written procedure on the handling and storage of laundry and linen. The staff member indicated the facility follows the guidelines from The Healthcare Laundry Accreditation Council (HLAC). The staff member confirmed the clean linen stored in the Morgue should have been covered or placed in cabinets to protect against contamination.</p> <p>3. The HLAC guidelines for</p>		<p>numerous occasions between 2/04/13 and 2/12/13 and established the following additional corrective actions related to Tags 0612 and 1118:1. Environmental Services removed all supplies from cabinets and shelving units in the Autopsy room on 2/07/13.2. Facilities Services staff repaired several cabinet doors, removed open shelving unit and cleaned shower floor drain on 2/08/13.3. Lab supplies are no longer stored in the Morgue effective 2/4/13. The diener now has responsibility to bring lab supplies necessary for each individual autopsy and for the removal of all excess lab supplies upon completion of autopsy.4. Facility Services began performing monthly preventative maintenance on all plumbing fixtures, floor drains, light fixtures, ventilation units, and doors on 2/08/13.5. Laboratory staff began performing monthly preventative maintenance on the eye wash station on 2/08/13.6. Environmental Services assumed responsibility for routine cleaning, supplying clean linen, and for performing daily inspections to maintain cleanliness on 2/12/13.7. Environmental Services will organize all supplies located within the Morgue by 2/16/13. Inspection of the Morgue has been added to the monthly environment of care rounding. Compliance data is reported monthly to Hospital</p>				

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	storage of clean laundry and linen was to store in a dry location. The laundry and linen should be covered or wrapped in plastic to protect against dust, dirt and other soil residue.		Leadership.	

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S0754	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(f)(5)</p> <p>(f) All inpatient records, except those in subsections (g), shall document and contain, but not be limited to, the following:</p> <p>(5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.</p> <p>Based on policy and procedure review, document review, medical record review, and personnel interview, the facility failed to ensure properly executed Consent for Treatment, Operative Consent Form, and/or Anesthesia Consent Form for 6 of 20 (N1, N4, N6-N8, and N11) closed patient medical records reviewed.</p> <p>Findings:</p> <p>1. Policy titled, "Informed Consent", with a reapproval date of 4/13/10, was reviewed on 1/17/13 at approximately 12:30 PM, and indicated on pg. 2, under Special Instructions section, point C., "Memorial staff assumes responsibility for assuring the Informed Consent form is completed and signed prior to the treatment being performed...If the forms are not completed and signed by all</p>	S0754	<p>The Director of Risk Management is responsible for corrective and preventative actions. All consent form templates have been audited (and revised as necessary) for the presence of signature, date and time prompts for physician, patient and witness. The Anesthesiologists were advised at the time of survey of the need to sign, date and time anesthesia consents. All staff were educated via email on 2/19/13 of the requirement for physicians, patients and witnesses to sign, date &amp; time all consent forms. The email included a flyer to be posted as a reminder in all clinical areas. All physicians will receive additional education on requirements to sign, date and time consent forms via the March, 2013 Medical Staff Newsletter. The Director of Risk Management is conducting a random monthly audit on 70</p>	02/19/2013			

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	<p>required parties, it shall be brought to the attention of the physician and/or anesthesiologist."</p> <p>2. Review of Rules and Regulations of the Medical Staff, with a reapproval date of 2/21/12, was review on 1/17/13 at approximately 12:30 PM, and indicated on pg. 11, under Authentication section, "The parts of the medical record that are the responsibility of the Practitioner must be legible, complete, dated, timed, and authenticated by the Practitioner."</p> <p>3. Review of closed patient medical records on 1/16/13 at approximately 2:48 PM, indicated patient:</p> <p>A. N1:</p> <p>a. per Operative Report dated 1/16/13 underwent a left carotid endarterectomy.</p> <p>b. Consent for Treatment lacked the time of the patient's signature, and the date and time of the witnesses signature.</p> <p>c. Operative Consent Form lacked the time of the patient's signature and the time of the witnesses signature.</p> <p>d. Anesthesia Consent Form lacked the time of the patient's signature and the time of the witnesses signature.</p> <p>e. unable to determine if the consents were signed by the patient and/or witness prior to the start of the surgical procedure.</p> <p>B. N4:</p> <p>a. per Operative Report and</p>		<p>patient records to assess ongoing compliance with signature, date and time requirements on consent forms. Results of the audit are reported to Hospital Leadership monthly.</p>				

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	<p>Intraoperative Record dated 1/16/13 underwent a bilateral carotid arteriogram that started at 9:43 AM.</p> <p>b. Operative Consent Form lacked the time of the patient's signature.</p> <p>c. Anesthesia Consent Form lacked the time of the patient's signature and the time of the physician's signature.</p> <p>d. unable to determine if the consents were signed by the patient and/or witness prior to the start of the surgical procedure.</p> <p>C. N6:</p> <p>a. per Operative Report and Intraoperative Record dated 9/5/12 underwent a right craniotomy with aneurysm clipping that started at 13:37 PM.</p> <p>b. Operative Consent Form lacked the date and time of the patient's signature.</p> <p>c. unable to determine if the consent was signed by the patient prior to the start of the surgical procedure.</p> <p>D. N7:</p> <p>a. per Operative Report and Intraoperative Record dated 8/6/12 underwent a left wire localized partial mastectomy, left axillary dissection that started at 11:04 AM.</p> <p>b. Anesthesia Consent Form lacked the date and time of the patient's signature and the time of the witnesses' signature.</p> <p>c. unable to determine if the consents were signed by the patient and/or witness prior to the start of the surgical procedure.</p>			

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	<p>E. N8:</p> <p>a. per Operative Report and Intraoperative Record dated 8/31/12 underwent placement of a port-a-cath that started at 12:26 PM.</p> <p>b. Consent for Treatment lacked the time of the patient's signature, and the date and time of the witnesses signature.</p> <p>c. Operative Consent Form lacked the time of the patient's signature and the time of the physician's signature.</p> <p>d. Anesthesia Consent Form lacked the time of the patient's signature.</p> <p>e. unable to determine if the consents were signed by the patient and/or witness prior to the start of the surgical procedure.</p> <p>F. N11:</p> <p>a. Consent for Treatment lacked the date and time of the patient's signature, and the signature, date, and time of the witnesses' signature.</p> <p>4. Personnel P10 was interviewed on 1/16/13 at approximately 4:00 PM and confirmed, Consent for Treatment, Operative Consent Form, and/or Anesthesia Consent Forms need to be signed, dated, and timed by the patient (if able) and the witness and the physician (if applicable) prior to the start of the procedure. These were not complete for patients N1, N4, N6-N8, and N11 when reviewed.</p>			

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S0952	<p>410 IAC 15-1.5-6 NURSING SERVICE 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 and procedure review, medical record review, and personnel interview, the facility failed to ensure blood transfusions were administered in accordance with approved medical staff policies and procedures for 7 of 10 (N21, N23, N25-N28, and N29) closed patient medical records reviewed who received transfusion of blood products</p> <p>Findings:</p> <p>1. Policy titled, "Blood Transfusion, including Blood Components (from Blood Bank)", with a reapproval date of 11/1/10, was reviewed on 1/17/13 at approximately 1:10 PM, and indicated on pg:</p> <p>a. 4, under Procedure section, point:</p> <p>i. 14. c. and e., "take temperature (T), pulse (P), respirations (R), and blood pressure (BP) at the end of the first 15 minutes of administration (documentation</p>	S0952	The Chief Nursing Officer is responsible for corrective and preventative actions. An investigation of current practice and documentation related to blood transfusions was completed on 2/21/13. The investigation revealed the need for re-education of staff on blood transfusion protocol and documentation. In addition, it was determined that language in the policy "Blood Transfusion, including Blood Components" which stated "documentation within a 10 minute (or 20 minute) window of this time is acceptable) was misinterpreted which led to variation in documentation. The referenced language was removed from the policy on 2/21/13. Staff will be re-educated the week of February 25, 2013 on blood transfusion protocol including requirements to document completion of transfusion and whether or not a transfusion reaction occurred.	02/28/2013			

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	<p>within a 10 minute window of this time is acceptable)...take T, P, R, and BP upon completion of the blood transfusion."</p> <p>ii. 18., "Transfusion of one unit must be completed within a maximum time of 4 hours from removal from the Blood Bank."</p> <p>b. 5, point 24. c., "At completion of transfusion...complete and document all remaining assessments."</p> <p>2. Review of closed patient medical records on 1/17/13 at approximately 10:08 AM, indicated patient:</p> <p>A. N21:</p> <p>a. per BB Transfusion Investigation Worksheet dated 1/11/13 infusion of a unit of packed red blood cells (PRBCs) was started at 1200.</p> <p>b. per Electronic Medical Record dated 1/11/13, vital signs were documented at 1220, this is 20 minutes past the start of infusion. Time transfusion stopped was lacking, therefore vital signs recorded at 1402 could not be determined to be post transfusion.</p> <p>B. N23:</p> <p>a. per Electronic Medical Record dated 10/11/12, infusion of a 2nd unit of PRBCs was started at 1900. Time transfusion stopped, post transfusion vitals, and whether or not a transfusion reaction occurred were lacking.</p>		<p>Staff will also be educated to document in real time. Education will occur via email, department 'jump start' meetings, and staff meetings. Educational flyers will also be posted in each clinical area the week of February 25, 2013. The Vice President of Medical Staff Affairs, Quality &amp; Safety will conduct a random closed chart audit for 4 consecutive months to measure compliance with documentation requirements related to blood transfusions. Result of the audit will be reported to Hospital Leadership monthly.</p>		

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	<p>C. N25: a. per Electronic Medical Record dated 10/30/12, infusion of a unit of PRBCs was started at 1438, vital signs were documented at 1500, this is 22 minutes past the start of infusion.</p> <p>D. N26: a. per Electronic Medical Record dated 10/23/12, infusion of a unit of PRBCs was started at 0120. Documentation of whether or not a transfusion reaction occurred was lacking.</p> <p>E. N27: a. per Electronic Medical Record dated 11/19/12, infusion of a unit of PRBCs was started at 1020, vital signs were documented at 1050, this is 20 minutes past the start of infusion. Time transfusion stopped was lacking, therefore vital signs recorded at 1332 could not be determined to be post transfusion. Documentation of whether or not a transfusion reaction occurred was lacking.</p> <p>F. N28: a. per Electronic Medical Record dated 11/27/12, infusion of a unit of PRBCs was started at 2130. Documentation of whether or not a transfusion reaction occurred was lacking.</p>			

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	<p>G. N29:</p> <p>a. per Electronic Medical Record dated 11/7/12, infusion of a unit of PRBCs was started at 1754, vital signs were documented at 1821, this is 27 minutes past the start of infusion.</p> <p>3. Personnel P10 was interviewed on 1/16/13 at approximately 4:00 PM and confirmed, vital signs and time transfusion of PRBCs were not documented per facility policy and procedure. Also, documentation of whether or not a transfusion reaction occurred was lacking, which is required per facility policy and procedure.</p>			

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S1014	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7(c)</p> <p>(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.</p> <p>Based on observation, document review, and interview, the facility failed to follow their policy regarding safe storage of medication in two patient care areas (C/S room and orthopedics).</p> <p>Findings included:</p> <p>1. During the tour of OR 2 in the obstetrical area at 10:45 AM on 01/16/13, accompanied by staff members #A10, A13, and A14, a twenty milliliter vial of Propofol and a ten milliliter vial of Succinylcholine were observed in an unlocked drawer of the anesthesia machine. No staff were observed in the room or surrounding hallway. Staff member #A13 indicated the anesthesiologists did not want the drawer locked, but confirmed housekeepers cleaned the room.</p> <p>2. During the tour of the Orthopedic unit at 2:45 PM on 01/16/13, accompanied by</p>	S1014	<p>The Chief Nursing Officer is responsible for corrective and preventative actions. All unsecured medications in both locations were removed at time of survey. In the Child Birth Unit signs stating "No Unsecured Meds in Drawer" were placed in the drawer of the anesthesia machines on 2/05/13. Intubation kits were moved to a locked drawer in the Pyxis automated medication dispensing cabinet on 2/05/13. Physicians and anesthesia assistants were re-educated on policy via email and face to face discussion on 2/05/13. Ongoing education will be conducted during monthly staff meetings and utilizing email and department newsletters. Anesthesia assistants will inspect anesthesia machine drawers daily for unsecured medications and report discovery of all medications in drawers to Director of Child Birth Unit immediately. Director of Child Birth Unit will then report physicians on duty to the Vice</p>	02/11/2013			

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	<p>staff members #A10, A19, and A20, an unlocked medication cart was observed in a connecting hallway on the patient unit. The hallway was open, but signs on each entrance indicated it was only for authorized personnel. No staff was in the hallway or immediate area. Staff members #A19 and A20 indicated the cart was used as a medication cart and had an automatic locking system that would lock the cart in 3- 5 minutes. However, after waiting 3- 5 minutes, the cart did not lock.</p> <p>At 9:30 AM on 01/17/13, staff member #A10 indicated misinformation had been provided yesterday and the cart was only used for supplies, not medications, and it was left unlocked as it did not have an automatic locking system.</p> <p>At 10:00 AM on 01/17/13, the Orthopedic unit was revisited and the medication cart was again unlocked and unattended. One of the drawers was opened and a plastic bag containing one tablet of Captopril for a specific patient was found. The bag indicated the quantity was two tablets. Staff member #A20 indicated the medication should not be in the cart.</p> <p>3. Review of the facility policy "Monthly Inspections of Medication Storage Areas", effective 05/01/11, indicated, "2. Each</p>		<p>President of Medical Staff Affairs. Compliance data will be reported monthly to Hospital Leadership. The cart located in the Orthopedic Unit (8 South) is intended to be used only as a work surface. The single tablet of Captopril was removed and appropriately discarded at the time of survey. On 2/11/13 all drawers were removed from the cabinet to prevent the cabinet from being used for storage purposes. Ongoing compliance will be monitored utilizing the existing monthly patient safety monitoring tool which includes an indicator for inspections related to unsecured medications. Patient safety monitoring results are reported to Hospital Leadership and Nursing Quality &amp; Safety Council on a monthly basis.</p>				

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	medication storage area shall be locked, and/or under the direct supervision of personnel approved to handle the medications at all times."			

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S1022	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(B)</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>(B) Appropriate storage conditions. Based on observation, policy and procedure review, and personnel interview, the facility failed to ensure appropriate storage conditions for high alert medications according to facility policy and procedure for 1 of 7 (Post Anesthesia Care Unit [PACU]) areas toured.</p> <p>Findings:</p> <p>1. While on tour of facility on 1/16/13 at approximately 11:30 AM, in the company of P3, P8, and P9, the following was observed in the PACU Medication Room:</p> <p>A. lack of label with number on container holding high risk/high alert medication Rocuronium. Should have been label #3 on this container in the Automated Medication Dispensing Cabinet.</p> <p>B. high risk/high alert medications of Rocuronium and Succinylcholine were</p>	S1022	The Director of Pharmacy is responsible for corrective and preventative actions. On January 25, 2013 the medication refrigerator in the PACU was reorganized to allow segregated storage of all high alert medications. All segregated bins were labeled with the appropriate numbered label corresponding to the bin number identified in the Pyxis. (Pictures of PACU refrigerator taken on 1/25/13 following corrective action have been uploaded as part of this response.) Pharmacy staff conduct monthly floor inspections, which include all medication storage locations, to ensure medications (including high alert medications) are stored according to policy & procedure.	01/25/2013			

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	<p>not clearly labeled as such and/or separated appropriately from the general medication inventory of injectable medications such as Cardizem and Nimbex.</p> <p>2. Policy titled, "Automated Medication Dispensing Cabinets (ADC)" with a reapproval date of 2/21/12, was reviewed on 1/16/13 at approximately 12:45 PM, and indicated on pg. 3, under Medication Removal Process section, point 5., "The ADC will prompt the user to remove the medication from the designated drawer and pocket."</p> <p>3. Policy titled, "High Alert Medications" with a reapproval date of 11/20/12, was reviewed on 1/16/13 at approximately 12:45 PM, and indicated on pg. 1, under Procedure section, point 4., "Overall general strategies that can be used to reduce the risk of errors include limiting access to high alert medications, using auxiliary labels and automated alerts. Other strategies include standardizing the...storage...of these products, and employing redundancies such as automated or independent double-checks when necessary."</p> <p>4. Personnel P9 was interviewed on 1/16/13 at approximately 11:35 AM and confirmed the number label was missing</p>			

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	on the container holding the high risk/high alert medication Rocuronium in the ADC and that high risk/high alert medications should be clearly labeled as such and/or separated appropriately from the general medication inventory of injectable medications.			

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S1118	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 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, review of policies and procedures, manufacturer's recommendations and staff interview, the facility failed to maintain the hospital environment and equipment in such a manner that the safety and well-being of patients, visitors, and/or staff were assured in six (6) instances: Morgue, Interventional Radiology, Navarre Radiology Department, Kitchen, Surgery Department and 7 Intermediate.</p> <p>Findings included:</p> <p>1. At 2:15 PM on 1/15/2013, the Morgue was toured. The back room of the Morgue had a shower stall with a 10-inch shower floor drain. The floor drain was caked with encrusted debris that was closing the drain holes. A sewer smell was coming from the floor drain. The room also had a refrigerator. The</p>	S1118	<p>Response for findings 1, 2 &amp; 5 related to the Morgue: The Hospital Infection Preventionist is responsible for corrective actions. The Director of Environmental Services is responsible for preventative actions. On 2/01/13 a team, including the Sr. Director of Operations, Lab Manager, House Float Director, Environmental Services Director, Facilities Director, and Infection Preventionist, was formed to establish a process, identify areas of responsibility, identify needed repairs and improvements to equipment and/or structure and to organize supplies &amp; equipment in the morgue. The team met on numerous occasions between 2/04/13 and 2/12/13 and established the following additional corrective actions related to Tags 0612 and 1118: 1. Environmental Services removed all supplies from cabinets and</p>	02/16/2013			

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	<p>refrigerator contained a package that was leaking an unknown substance on to the refrigerator floor. The cabinets throughout the Morgue were inspected and they were unorganized, and unwanted trash and debris was also observed in the cabinets. A green wall mounted cabinet designated for the police was observed with heavy amount of trash and debris within the cabinet beside a stack of police forms.</p> <p>2. At 1:05 PM on 1/16/2013, staff member A4 indicated the hospital does not have a policy or procedure on who has the responsibility of maintaining the cleanliness of the Morgue. The Pathologists maintain the autopsy table and the walk-in cooler only. The sanitation of the Morgue has slipped through the cracks.</p> <p>3. At 2:10 PM on 1/16/2013, the Radiology Department was toured at Navarre building offsite. In ultrasound room #1, a hand sanitizer was observed mounted directly above the light switch. The dispenser does not have a tray underneath it to collect the excess liquid. Excess debris from the sanitizer was observed caked on the light switch plate.</p> <p>4. At 10:50 AM on 1/17/2013, the Interventional Radiology Department was</p>		<p>shelving units in the Autopsy room on 2/07/13.2. Facilities Services staff repaired several cabinet doors, removed open shelving unit and cleaned shower floor drain on 2/08/13.3. Expired Lab supplies and sexual assault evidence collection kit were removed and appropriately discarded at the time of survey. Lab supplies are no longer stored in the Morgue effective 2/4/13. The diener now has responsibility to bring lab supplies necessary for each individual autopsy and for the removal of all excess lab supplies upon completion of autopsy.4. Facility Services began performing monthly preventative maintenance on all plumbing fixtures, floor drains, light fixtures, ventilation units, and doors on 2/08/13.5. Laboratory staff began performing monthly preventative maintenance on the eye wash station on 2/08/13.6. Environmental Services assumed responsibility for routine cleaning, supplying clean linen, and for performing daily inspections to maintain cleanliness on 2/12/13.7. Environmental Services will organize all supplies located within the Morgue by 2/16/13. Inspection of the Morgue has been added to the monthly environment of care rounding. Compliance data is reported monthly to Hospital Leadership. Response to findings 3 &amp; 4 related to location of hand sanitizer: The Director of Facilities</p>				

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	<p>toured. A light switch located between procedure rooms #3 and #4 was observed with a hand sanitizer mounted directly above the switch. Residue from the sanitizer was observed on the switch plate. The sanitizer bottle had a warning label indicating it was Flammable.</p> <p>5. During tour of the morgue on 1-14-13 between 3:30 PM and 4:00 PM, while accompanied by Staff Member L6, the following expired supplies were observed:</p> <p>a. Three "COPan" swabs, lot number "503CS01", expiration date "2012/10" located in the "risk management" refrigerator in the morgue bathroom.</p> <p>b. The the wall cabinet over the counter:</p> <p>1. Three "BBL Culture" swabs, lot number "029A08 L. 63L405", expiration date "2012/05"</p> <p>2. One "BBL Culture" swab, lot number "010L41 L. YP5I05", expiration date "2010/01"</p> <p>3. Four "BBL Culture" swabs, lot number "029D10 L. N1TS05", expiration date "2010/06"</p> <p>4. Three "BBL Culture" swabs, lot number "029H02 L. SUS905", expiration date "2011/03"</p> <p>5. One "BBL Culture" swab, lot number "029N46 L. PH2C05", expiration date "2011/02"</p>		Services is responsible for corrective and preventative actions. The hand sanitizers in both locations were moved away from electrical switches on 2/05/13. Ongoing compliance housewide will be monitored as part of the monthly environment of care rounds and reported monthly to Hospital Leadership.				

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	<p>6. Three gray top, 6.0 milliliter (mL) "BD Vacutainer" tubes, lot number "0225671", expiration date "2011-05"</p> <p>7. Two gray top, 6.0 mL "BD Vacutainer" tubes, lot number "9149079", expiration date "2010-10"</p> <p>8. Three blue top, 4.0 mL "BD Vacutainer" tubes, lot number "9303182", expiration date "2010-11"</p> <p>9. One blue top, 4.0 mL "BD Vacutainer" tube, lot number "9140113", expiration date "2010-06:"</p> <p>10. One gold top, 6.0 mL "BD Vacutainer" tube, lot number "0076313", expiration date "2011-03:"</p> <p>11. Three gold top, 6.0 mL "BD Vacutainer" tubes, lot number "9198449", expiration date "2010-07"</p> <p>12. Three red top, 6.0 mL "BD Vacutainer" tubes, lot number "0056957", expiration date "2011-07"</p> <p>13. One red top, 6.0 mL "BD Vacutainer" tube, lot number "117089", expiration date "2012-09"</p> <p>14. One green top, 4.0 mL "BD Vacutainer" tube, lot number "9127092", expiration date "2010-09"</p> <p>c. In a green, metal wall cabinet:</p> <p>1. One "State of Indiana Sexual Assault Evidence Collection Kit", lot number "0211001", expiration date "Dec. 2012"</p> <p>2. One "State of Indiana Sexual Assault Evidence Collection Kit", lot</p>						

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	<p>number "2659", expiration date "Sept. 2006"</p> <p>6. In interview on 1-14-13 between 3:30 PM and 4:00 PM, Staff Member #L6 acknowledged the above findings.</p> <p>7. Review of policies and procedures on 1-16-13 between 3:17 PM and 3:40 PM indicated a policy / procedure titled: "Food and Supply Storage", which read: "Department Manager, Supervisor...2. Ensures that all supplies are stored 6 inches above the floor and 18 inches below the sprinkler head level in sprinkled storage areas or 24 inches from the ceiling in nonsprinklered storage areas."</p> <p>8. During a tour of the main production kitchen on 1-15-13 between 10:45 AM and 3:30 PM, while accompanied by Staff Members #L5 and #L8, the following was observed:</p> <ul style="list-style-type: none"> <li>a. A "Frito Lay" box, soda, and other miscellaneous boxes stored less than 18 inches from the ceiling in the non-sprinklered reduced oxygen packaging area of the kitchen.</li> <li>b. Several boxes of paper products stored greater than 18 inches from the ceiling in the non-sprinklered cold preparation area.</li> <li>c. Water bottles stored greater than 18</li> </ul>			

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	<p>inches from the ceiling in the non-sprinklered soda storage area.</p> <p>9. In interview on 1-15-13 between 10:45 AM and 3:30 PM, Staff Member #L5 acknowledged the above findings.</p> <p>10. While on tour of facility on 1/16/13 at approximately 1:13 PM, in the company of P3 and P9, it was observed in the scrub sink outside operating room:</p> <p>A. 1, a one gallon bottle of Enzymatic Cleaner for surgical instruments.</p> <p>B. 4, a Mayfield Headrest with what appeared to be blood on it and used surgical equipment.</p> <p>11. Policy Policy titled, "Environmental Sanitation" with a reapproval date of 2/21/12, was reviewed on 1/16/13 at approximately 3:41 PM, and indicated on pg. 2, under Terminal Cleaning section, point B., "All areas and equipment in the surgical suite should be cleaned according to an established routine by Environmental Services. These include, but are not limited to, air conditioning grills/filters, cabinets, shelves, walls, ceilings, overhead tracks, offices, lounges, and locker rooms...Sanitation practices should provide a safe, clean environment for the surgical patient and personnel while keeping disposal costs at a minimum."</p>			

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	<p>12. Personnel P9 was interviewed on 1/16/13 at approximately 1:23 PM and confirmed the scrub sinks outside the surgical operating rooms should not have any equipment used or not and/or cleaning supplies in them.</p> <p>13. During the tour of the kitchen at 10:45 AM on 01/15/13, four bottles of Vital 1.5 Cal. tube feedings were observed exposed to light, stored on a wire shelf in the dry storage area. The manufacturer's label indicated the bottles contained light sensitive nutrients.</p> <p>14. During the tour of the 7 intermediate unit at 3:10 PM on 01/16/13, accompanied by staff members #A10 and A21, three bottles of Jevity 1.5 Cal. tube feedings were observed exposed to light, stored on an open counter in the pantry. The manufacturer's label indicated the bottles contained light sensitive nutrients.</p> <p>15. The facility policy "Enteral Nutrition/Delivery", approved 05/04/09, indicated, "7. Formula stored in boxes to prevent light sensitivity."</p>			

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S1160	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(1)</p> <p>(d) The equipment requirements are as follows:</p> <p>(1) All equipment shall be in good working order and regularly serviced and maintained.</p> <p>Based on observation and staff interview, the facility failed to ensure the Therm Sure Dryer located in the Sleep Disorder Offsite was maintained and failed to regularly service the following 1 of 3 pieces of equipment reviewed (microwave).</p> <p>Findings included:</p> <p>At 8:57 AM on 1/16/2013, the Sleep Disorders Center offsite was toured. The facility has a washing unit that washes the hoses and masks used for the center. After the items are washed, the items are hung up in a Therma Sure Dryer. The inside of the upright drying unit was observed with heavy accumulation of rust and paint peeling. There were cleaned items on the floor of the dryer resting on the rusty surface.</p>	S1160	<p>The Executive Director of Operations is responsible for corrective actions. The Director of Biomedical Engineering is responsible for preventative actions related to the Therm Sure Dryer. The Director of Nutritional Services is responsible for preventative actions related to the microwave located in the Canteen area. Biomedical Engineering staff inspected the Therm Sure Dryer located at the Sleep Disorder Center on 2/06/13 and following discussion with the Executive Director of Operations determined the best corrective action is to replace the dryer. A new dryer is being acquired through the hospital capital expenditure process. The anticipated date of installatino is 3/13/13. Staff were re-educated on the appropriate use of the dryer on 2/06/13 via face to face discussion. The Therm Sure Dryer has been placed on the annual preventative maintenance schedule to prevent reoccurrence. The daily cleaning of the microwave located in the Canteen area was added to the</p>	03/13/2013

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	<p>1. During tour of the "Canteen Kiosk" on 1-15-13 between 2:30 PM and 3:15 PM, while accompanied by Staff Members #L5, #L7, #L8, and #L9, a "Panasonic" microwave was observed in the waiting room adjacent to the "Canteen Kiosk" on the second floor.</p> <p>2. In interview on 1-15-13 between 2:30 PM and 3:15 PM, Staff Member #L7 acknowledged the above finding and conveyed the hospital did not have a preventative maintenance schedule for the above mentioned microwave.</p>		<p>daily cleaning responsibilities for Nutritional Services on 2/01/13. Ongoing compliance with the daily cleaning of all Nutritional Services microwave ovens located in the Cafeteria and Canteen areas will be monitored daily as a part of the Nutritional Services Management rounding. Rounding results will be reported to Hospital Leadership on a monthly basis.</p>		