

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001012	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 12/12/2013
NAME OF PROVIDER OR SUPPLIER THE EYE SURGICAL CENTER OF FORT WAYNE LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 321 E WAYNE ST FORT WAYNE, IN 46802		
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Q000000	<p>The visit was for a re-certification survey.</p> <p>Facility Number: 005393</p> <p>Survey Date: 12-10-13 to 12-12-13</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 12/20/13</p>	O000000			

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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Q000043	<p>416.41(c) DISASTER PREPAREDNESS PLAN (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. (2) The ASC coordinates the plan with State and local authorities, as appropriate. (3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.</p> <p>Based upon document review and interview, the center failed to follow its policy/procedure regarding emergency preparedness and perform periodic disaster and emergency preparedness drills for 4 of 4 drills in 2013.</p> <p>Findings:</p> <p>1. The policy/procedure Emergency Operations and Disaster Plan (approved 2-12) indicated the following: " The ASC will conduct one (1) drill each calendar quarter of the internal emergency and disaster preparedness plan. "</p> <p>2. On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation of disaster drills performed in 2013 and none was provided prior to exit.</p>	Q000043	The Surgery Manager and Safety Officer will ensure quarterly disaster drills are performed, documented, and reviewed by Safety and QA committees and at governing board meetings. This will begin the first quarter of 2014.	01/06/2014			

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	3. During an interview on 12-11-13 at 1500 hours, staff A1 confirmed that no disaster drill documentation was available.			

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Q000141	<p>416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. Based on policy and procedure review, document review, and staff interview, the surgery manager failed to implement the facility policies regarding monthly staff meetings in either 2012 or 2013 and follow up patient phone calls for 5 patients (pts. #1, #4, #5, #10 and #13).</p> <p>Findings:</p> <ol style="list-style-type: none"> review of the policy and procedure "Staff Meetings", policy number 5.03, with a last revised date of 1/10, indicated: <ol style="list-style-type: none"> under "Policy", it reads: "Meetings of center personnel shall be conducted on a minimum monthly basis for the purpose of communication which may include the following topics: reviewing patient care services..." review of the staff meeting minutes binder indicated that only two meetings were held in 2012, on 4/4/12 and 10/2/12, and that none were documented for 2013 interview with staff member #60, the RN (registered nurse) surgery manager, at 12:30 PM on 12/12/13, indicted that no 	Q000141	The Eye Center of Fort Wayne will begin holding monthly staff meetings to discuss any new business and review policy and procedures. The staff will be given an inservice to review the policy on completing post op phone calls. The surgery manager will ensure that meetings are held and documented and reported per facility policy.	01/10/2014	

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	<p>staff meetings have occurred as required by facility policy</p> <p>4. review of the policy and procedure "Post-Operative Telephone Call", policy number 5.37, with a last revised date of 1/11, indicated:</p> <p>a. under "Practices & Procedures", it reads: "...4. In the event the patient is not contacted on the initial attempt, one additional attempt will be made..."</p> <p>5. review of patient medical records indicated that patients #1, #4, #5, #10 and #13 only received one follow up phone call in which the staff member noted "left message" on the form in the patient's chart</p> <p>6. interview with staff member #60 at 2:15 PM on 12/11/13 indicated this staff member was unaware that there was a policy that required a second attempt for follow up with a patient if there was no answer on the first attempt</p>			

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Q000181	<p>416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. Based on policy and procedure review, observation, and staff interview, the facility failed to ensure that medications were accessible to only authorized personnel in two locations.</p> <p>Findings: 1. review of the policy and procedure "Pharmaceutical Services", policy number 8.01, with a last revised date of 2/10, indicated: a. under "Policy", it reads: "Pharmaceutical supplies and services shall be maintained and controlled in accordance with acceptable ethical and professional practices and all legal requirements."</p> <p>2. at 4:00 PM on 12/11/13 while on tour of the "back hallway" of the surgical area (outside the OR suites), it was observed that an unlocked refrigerator contained several multidose vials of IV medications (in a basket with one of the surgeon's names printed on a post it note)</p> <p>3. while on tour of the surgical area at 4:15 PM on 12/11/13, it was observed in OR (operating room) "A" that a cart was unlocked and contained IV (intravenous)</p>	O000181	The refrigerator with several multidose vials of IV medications is now kept locked unless surgery is being performed. It is unlocked during the surgery day and locked at the conclusion of surgery. The IV medications Mannitol and Zofran have been removed from the unlocked cart in surgery room A. They are kept in a locked cabinet. Policy 8.01 has been changed to reflect that only authorized personnel should have access to medications. The surgery manager will ensure that the refrigerator remains locked during non-surgery days and that the policy is followed. Please see at attached Policy 8.01.	12/31/2013			

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	<p>medications: Mannitol--2 vials 50 cc each, and Zofran--2 vials 10 cc each</p> <p>4. interview with staff member #60, the RN (registered nurse) surgery manager at 4:15 PM on 12/11/13 indicated:</p> <p>a. both areas with IV medications were unsecured and accessible to the contracted housekeeping staff and other unauthorized personnel</p> <p>b. the policy (8.01) fails to specify that only authorized personnel should have access to medications</p>				

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Q000223	<p>416.50(b) NOTICE - PHYSICIAN OWNERSHIP The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing. Based on document review and interview, the center failed to ensure that notice of physician ownership in the center was provided to patients prior to the start of the procedure.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Patient ' s Bill of Rights/Grievance Process (approved 2-12) and the document Patient ' s Bill of Rights Eye Surgical Center of Fort Wayne (approved 2-12) indicated the following: " Notice of disclosure of the physician financial interest or ownership in the ASC facility must be in writing and furnished to the patient in advance of the date of the procedure ... " The policy/procedure, Bill of Rights document provided to patients and posted at the center and the Eye Surgical Center of Fort Wayne surgical consent form failed to indicate by name the physician(s) with ownership in the surgery center. During an interview on 12-11-13 at 1355 hours, staff A1 confirmed that the 	O000223	The patient Bill of Rights, consent forms, and brochures will be updated to contain the disclosure of Dr. Parent as a physician with ownership in the ASC. The surgery manager will oversee the changing of these documents. Please see attached consent and Patient Bill of Rights. These are awaiting approval of the chief executive officer and governing board.	01/12/2014			

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	policy/procedure and brochure lacked the required information.			

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Q000242	<p>416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>Based on policy and procedure review, document review, personnel file review, and interview, the infection control committee failed to implement its policies related to: employee immunization status (staff N1, N4, and N6); exposure from needle/blade sticks (staff N4 and N13); and related to TB (tuberculin) testing for 2 staff members (staff N2 and N6).</p> <p>Findings:</p> <p>1. Review of the policy and procedure "Blood Borne Pathogen Testing of Patients and Employees", policy number 10.15, with a revised date of 2/10, indicated:</p> <p>a. under "Policy", it reads: "In the event of a blood borne pathogen exposure, serologic testing is needed on the source person and the recipient for adequate medical treatment..."</p> <p>2. Review of the policy and procedure "Blood Borne Disease Exposure Control Plan", policy number 10.14, with a</p>	O000242	<p>3. Staff member N1 was sent for Varicella titer to be drawn-awaiting results; Staff member N4 was sent to have Rubella and Rubeola titers drawn-awaiting results; Staff member N6 was sent for Varicella Titer to be drawn-awaiting results. 5. Staff members N13 and N4 signed a declination form for lab testing for Hepatitis A, B, and C, or for HIV after a "oasis blade" stick incident. The surgery manager counseled the employees concerning exposure. Both patients involved in the incidents were tested per policy and the results were negative. Employees N13 and N4 were notified of test results. The surgery manager will ensure that employees are offered Hepatitis A,B,C and HIV testing after exposure to blood or body fluids. The surgery manager will counsel employees concerning exposure. IGRA (Interferon Gamma Release Assay) blood test will be accepted in place of a negative Mantoux</p>	01/09/2014			

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	<p>revised date of 1/11, indicated:</p> <p>a. under "Practices & Procedures", it reads: "1. Employment Physical Examination A. An initial health physical, will be completed by a physician upon hire of each staff member. Proof of communicable diseases may be accepted if the employee has a copy from another health institution's records or from staff member's primary care physician of said communicable diseases. See attached Health Care Personnel Vaccination Recommendations for further information. These recommendations will be a guide as to what is needed for each staff member on hire." (* The attached document indicated a CDC (centers for disease control and prevention) document that indicated immunity to communicable diseases (Rubella, Rubeola, and Varicella) for HCWs (healthcare workers) would include: physician documentation of having had the disease, or a titer showing immunity to the disease, or the documentation of immunization for the communicable disease)</p> <p>b. under section "VI. Reporting and Processing Exposure to Infectious Disease", it reads: "...C.....2. The Surgery Manager will counsel employee/physician concerning exposure and the employee/physician will be requested to be tested and consent obtained if testing is</p>		<p>test, as long as it has been performed within the last 12 months. An annual Mantoux test will be required after. Staff member N6 will have annual Mantoux done 1/2014. Surgery manager will ensure all employees have current Mantoux testing on file.</p>				

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	<p>to take place. If employee/physician declines, a declination form should be completed..."</p> <p>3. review of employee medical records indicated:</p> <p>a. staff member N1 was hired 10/22/12 and had a self reported document stating the employee had previously had chickenpox</p> <p>b. staff member N4 was hired in 2010 and lacked any information related to rubella or rubeola immunity</p> <p>c. staff member N6 was hired 5/2/13 and lacked documentation related to varicella immunity</p> <p>4. interview with staff member #60, the RN (registered nurse) surgery manager, at 2:50 PM on 12/11/13 and 10:15 AM on 12/12/13, indicated:</p> <p>a. it was unknown that a self reported immunity to Varicella was not acceptable</p> <p>b. it was unclear why there was no rubella or rubeola information for staff member N4, nor Varicella information for staff member N6</p> <p>5. review of incident reports for the last 6 months indicated:</p> <p>a. staff member N13 had a left thumb stick from an "oasis blade" on 6/4/13 and lacked documentation of having had lab tests for Hepatitis A, B, and C, or for HIV</p>						

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	<p>(Human Immunodeficiency Virus), or a declination form indicating the staff member refused this testing</p> <p>b. staff member N4 had a finger stick with an "oasis blade" on 8/20/13 and lacked documentation of having had lab tests for Hepatitis A, B, and C, or for HIV (Human Immunodeficiency Virus), or a declination form indicating the staff member refused this testing</p> <p>6. Review of the policy and procedure "Tuberculosis Infection Control Program", policy number 10.16, with a reviewed date of 2/10, indicated:</p> <p>a. in section "C. Employees", it reads: "1. All new employees are required to provide documentation of recent (12 months) negative Mantoux (PPD-purified protein derivative) test results. If no documentation is available, a two-step PPD test will be completed...2. all employees shall have the PPD test performed annually..."</p> <p>7. review of employee files indicated:</p> <p>a. staff member N2 was hired 7/1/13 and had documentation of an IGRA (Interferon Gamma Release Assay)</p> <p>b. staff member N6 was hired 5/2/13 and had documentation of two step PPDs at another place of employment in October 2012, but lacked a PPD at the time of hire in May, 2013</p>						

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	<p>8. interview with staff member #60, the RN (registered nurse) surgery manager, at 3:00 PM on 12/10/13, indicated:</p> <p>a. regarding staff member N2: the TB policy (10.16) does not address IGRA testing, [if it will be accepted by the facility, would a PPD test be required at any time (either upon hire, or annually) if someone has had an IGRA performed?]</p> <p>b. staff member N6 should have had a PPD test performed upon hire in May, 2013</p>			

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S000000	<p>The visit was for a licensure survey.</p> <p>Facility Number: 005393</p> <p>Survey Date: 12-10-13 to 12-12-13</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 12/20/13</p>	S000000		

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S000104	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(a)(2)</p> <p>The governing body shall do the following:</p> <p>(2) Adopt bylaws and function accordingly.</p> <p>Based on document review and interview, the governing board (GB) failed to adopt and maintain its governing board bylaws for the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation including GB bylaws and none was provided prior to exit. During an interview on 12-11-13 at 1310 hours, staff A1 confirmed that no GB bylaws were available. During an interview on 12-11-13 at 1710 hours, board chairman A2 confirmed that no GB bylaws were available for review. 	S000104	The Governing Board of The Eye Surgical Center of Fort Wayne has procured Governing Board Bylaws from their attorney. The Chief Executive Officer and governing board will be reviewing and updating the bylaws. The Chief Executive Officer and surgery manager will ensure the governing board bylaws are reviewed and maintained per facility policy	01/12/2014	

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S000106	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Review the bylaws at least triennially.</p> <p>Based on document review and interview, the governing board (GB) failed to review its board bylaws within the past three years.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation indicating at least a triennial review of the GB bylaws was performed by the GB and none was provided prior to exit. 2. The GB meeting minutes dated 5-23-2011 failed to indicate that a review of the GB bylaws had been performed. On 12-11-13 at 0930 hours, staff A1 was requested to provide additional documentation of GB meetings and none was provided prior to exit. 3. During an interview on 12-11-13 at 1310 hours, staff A1 confirmed that no documentation indicating a GB review of the GB bylaws was available. 	S000106	The governing board at The Eye Surgical Center of Fort Wayne will review the governing board bylaws triennially as stated per company policy. The Chief Executive Officer and Surgery manager will ensure that they are reviewed per policy.	01/12/2014	

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S000110	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(5)</p> <p>The governing body shall do the following:</p> <p>(5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up.</p> <p>Based on document review and interview, the governing board (GB) failed to document at least a quarterly review of the center management functions and/or quality assessment (QA) program for 8 of 8 quarters in 2012 and 2013.</p> <p>Findings:</p> <p>1. On 12-10-13 at 1030 hours and on 12-11-13 at 0930 hours, staff A1 was requested to provide documentation of GB meeting minutes for 2012 and 2013 and none was provided prior to exit.</p> <p>2. On 12-11-13 at 1310 hours, staff A1 confirmed that no documentation of GB meeting minutes was available.</p> <p>3. During an interview on 12-12-13 at 1200 hours, board chairman A2 confirmed that no quarterly GB meeting</p>	S000110	The governing board at The Eye Surgical Center of Fort Wayne will review the management functions and QA program quarterly as stated per company policy. The Chief Executive Officer and Surgery manager will ensure that this is done.	01/12/2014	

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	minutes were available.			

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S000116	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(2)(A-D)</p> <p>The governing body shall do the following:</p> <p>(2) Ensure the following:</p> <p>(A) The requests of practitioners, for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff.</p> <p>(B) Reappointments are acted upon at least biennially.</p> <p>(C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications.</p> <p>(D) This process occurs within a reasonable period of time as specified by the medical staff bylaws.</p> <p>Based on document review and interview, the governing board (GB) failed to document the appointment and reappointment of its medical staff within the past two years in accordance with its medical staff bylaws.</p> <p>Findings:</p> <p>1. The GB meeting minutes dated 5-23-2011 indicated that the board of directors met and reappointed MD10, MD12 and MD13 as active medical staff members. On 12-11-13 at 0930 hours,</p>	S000116	The credentialing committee will recommend reappointment of current medical staff at the next meeting and biennially as stated in the policy. The Governing board will review recommendation of reappointment of current medical staff and vote on such at the next meeting and biennially as stated in the policy. The surgery manager and chief executive officer will ensure that this is completed.	01/12/2014	

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	<p>staff A1 was requested to provide 2013 GB meeting documentation of current medical staff appointments and none was provided prior to exit.</p> <p>2. The medical staff meeting minutes dated 4-08-13 and 7-22-13 failed to indicate a credentials committee or medical staff action to recommend the medical staff candidates for reappointment to the governing board.</p> <p>3. During an interview on 12-11-13 at 1320 hours, staff A1 confirmed that no 2013 GB meeting documentation was available to indicate a medical staff reappointment action in accordance with the medical staff bylaws.</p>			

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S000122	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.</p> <p>Based on document review and interview, the governing board (GB) failed to review and approve the medical staff bylaws within the past three years.</p> <p>Findings:</p> <p>1. On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation indicating at least triennial GB approval of the medical staff bylaws, rules and regulations and none was provided prior to exit.</p> <p>2. The GB meeting minutes dated 5-23-2011 failed to indicate that a GB review of the medical staff bylaws had been performed. On 12-11-13 at 0930 hours, staff A1 was requested to provide additional documentation of GB meetings and none was provided prior to exit.</p> <p>3. During an interview on 12-11-13 at 1320 hours, staff A1 confirmed that no</p>	S000122	The Governing Board will review the medical staff bylaws and rules and change/approve said bylaws at the next meeting and triennially as stated in the policy. The surgery manager and chief executive officer will ensure that this is completed.	01/12/2014

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	documentation indicating GB review and approval of the medical staff bylaws was available.				

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S000172	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(L) Maintaining personnel records for each employee of the center 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-rays, as applicable.</p> <p>Based on policy and procedure review, employee file review, and staff interview, the governing board failed to implement its policy related to TB (tuberculin) testing for 2 staff members (staff N2 and N6).</p> <p>Findings: 1. Review of the policy and procedure "Tuberculosis Infection Control Program", policy number 10.16, with a reviewed date of 2/10, indicated: a. in section "C. Employees", it reads: "1. All new employees are required to provide documentation of recent (12 months) negative Mantoux (PPD-purified protein derivative) test results. If no documentation is available, a two-step PPD test will be completed...2.</p>	S000172	<p>IGRA (Interferon Gamma Release Assay) blood test will be accepted in place of a negative Mantoux test, as long as it has been performed within the last 12 months. An annual Mantoux test will be required after. Staff member N6 will have annual Mantoux done 1/2014. Surgery manager will ensure all employees have current Mantoux testing on file. See attached Policy 10.16</p>	01/10/2014			

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	<p>all employees shall have the PPD test performed annually..."</p> <p>2. review of employee files indicated:</p> <p>a. staff member N2 was hired 7/1/13 and had documentation of an IGRA (Interferon Gamma Release Assay)</p> <p>b. staff member N6 was hired 5/2/13 and had documentation of two step PPDs at another place of employment in October 2012, but lacked a PPD at the time of hire in May, 2013</p> <p>3. interview with staff member #60, the RN (registered nurse) surgery manager, at 3:00 PM on 12/10/13, indicated:</p> <p>a. regarding staff member N2: the TB policy (10.16) does not address IGRA testing, [if it will be accepted by the facility, would a PPD test be required at any time (either upon hire, or annually) if someone has had an IGRA performed?]</p> <p>b. staff member N6 should have had a PPD test performed upon hire in May, 2013</p>			

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S000226	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review, the governing board failed to ensure that the center developed and maintained a list of all contracted services, including the scope and nature of services provided, for 18 services.</p> <p>Findings:</p> <p>1. On 12-10-13 at 1030 hours, staff A1 was requested to provide a list of all contracted services and none was provided prior to exit.</p> <p>2. Review of center documentation indicated the following: alarm monitoring by V1, biohazardous waste disposal by V2, biomedical engineering by V3, fire extinguishers by V4, generator service by V5, heating/air conditioning service by V6, housekeeping by V7, laser service by V8, lens provider by V9, microscope service by V10, laboratory pathology services by V11, laundry service by V12, medical records consulting by V13, pharmacist consulting by V14, pharmacy</p>	S000226	Please see attached list of contracts. The surgery manager will review and revise the list of contracts as needed.	12/31/2013			

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	<p>supplies by V15, pest control by V16, radiology services by V17, and waste disposal service by V18.</p> <p>3. On 12-11-13 at 1250 hours, staff A1 confirmed that the center failed to maintain a list of contracted services.</p>			

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S000230	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based upon document review and interview, the governing board failed to ensure a periodic review of the center was performed by a minimum of 3 physicians having no financial interest in the center.</p> <p>Findings:</p> <p>1. The policy/procedure (approved 2-12) indicated the following: " The Utilization Review (UR) function is conducted by a committee consisting of at least two physicians and the surgery manager ...meetings of the UR committee at the center are held as often as necessary to conduct utilization review, but no less than quarterly. Minutes of committee activities are maintained " The policy/procedure failed to indicate the committee requirement for three (3)</p>	S000230	The Utilization Review policy has been changed to reflect that a minimum of three physicians having no financial interest in the center will perform a periodic review of facility charts. Dr. Eric Purdy, Dr. Pasalich, Dr. Padma Ponugoti, and Dr. Donald Lane are the appointed physicians, as seen on the organizational chart that is attached. The committee will meet quarterly and as needed and report findings to the governing board as the policy states. The surgery manager and chief executive officer will ensure that quarterly meetings and documentation take place. Please see attached QA Committee Structure and Policy 1.05.	01/12/2014	

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	<p>physicians having no financial interest in the center.</p> <p>2. The document Quality Assurance Committee Structure indicated the medical director A2 and one additional MD14 appointed to the UR committee.</p> <p>3. Documentation dated 4-12-13, 8-12-13 and 10-09-13 indicated only one physician (MD14) was involved with the UR activity.</p> <p>4. During an interview on 12-11-13 at 1350 hours, staff A1 confirmed that the UR policy/procedure lacked a requirement for 3 physicians without financial interest and confirmed that the UR committee membership indicated only one physician with no financial interest in the center.</p>				

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S000300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: Based on document review and interview, the center failed to develop and maintain an organized and effective quality assessment and improvement (QA) program to ensure ongoing monitoring of all services and important aspects of care.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Improvement Plan (approved 2-12) indicated the following: " Quality Improvement Committee (QIC) ...appointments to the QIC including chairman shall be made annually ...the QIC monitors the activities by review of the minutes and reports of the Utilization Review, Infection Control, Risk Management/Safety and Tissue Committees ...the QIC will meet at least quarterly ...all QI activities shall be appropriately documented ...the findings and recommendations of the committee</p>	S000300	The Eye Surgical Center of Fort Wayne has appointed members to the QIC committee and will be approved annually. Please see QA Committee structure attachment. The QIC will meet quarterly to review the minutes and reports of the UR, IC, Safety, and Tissue committees. Meeting minutes will be documented and the findings and recommendations, and corrective action will be reported to the board of directors, administration, and medical staff. Meeting minutes will include names of members that attended meetings. The surgery manager and chief executive officer will ensure that these meetings are held quarterly and properly documented.	01/12/2014			

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	<p>and corrective action will be communicated to the board of directors, administration and medical staff. "</p> <p>2. The document Quality Assurance Committee Structure failed to indicate a category and membership for the QIC.</p> <p>3. Documentation of QIC minutes dated 12-27-12, 4-10-13, and 7-22-13 failed to indicate the names of any members who attended the meetings.</p> <p>4. QIC minutes dated 12-27-12, 4-10-13, and 7-22-13 failed to indicate that utilization review, infection control, or safety committee minutes were reviewed and failed to document any findings, recommendations or corrective actions by the QIC.</p> <p>5. The 2013 QIC documentation failed to indicate that quarterly meetings were held in accordance with program requirements.</p> <p>6. During an interview on 12-12-13 at 1030 hours, staff A1 confirmed that the QIC minutes failed to document a review of utilization review, infection control, or safety committee minutes or otherwise incorporate the activity as a sub-committee function during the QIC meetings.</p>			

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	7. During an interview on 12-12-13 at 1230 hours, board chairman A2 confirmed that the center lacked documentation of quarterly QIC meetings in accordance with program requirements.			

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S000414	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1)</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>Based on policy and procedure review, document review, and interview, the infection control committee failed to meet quarterly.</p> <p>Findings: 1. review of the policy and procedure "Quality Improvement Plan", policy number 1.04, with a revised date of 1/11, indicated: a. on page 5 it reads: "Quality</p>	S000414	The Surgery manager and chief executive officer will ensure that the Infection Control committee will meet quarterly and document the meeting minutes as stated per company policy. Please see attached QA Committee Structure.	01/12/2014			

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	<p>Improvement Committee Function/Activities" "General...Infection Rates Pathology Reports..." b. on page 6 in the area "a. On Going Activities", it reads: "The broad scope of the responsibility of the Quality Improvement Committee's function necessitates the use and reliance on other committee and center functions to provide input and information. Specifically, the QIC (quality improvement committee) monitors the activities by review of the minutes and reports of the Utilization Review, Infection Control,...Committees."</p> <p>2. review of the Governing Board/Infection Control meeting minutes indicated the committee lacked quarterly meetings in 2013 by only meeting on 1/2/13 and 7/22/13</p> <p>3. interview with staff member #60, the RN (registered nurse) and surgery manager, and #61, the physician/administrator of the facility, at 12:30 PM on 12/12/13, indicated: a. the governing board, quality assurance, infection control committee is all the same b. there were only two meetings related to infection control in 2013</p>				

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S000428	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation.</p> <p>Based on document review and interview, the infection control (IC) committee failed to ensure that the operating room (OR) cleaning was performed in a safe and effective manner.</p> <p>Findings:</p> <p>1. The policy/procedure Housekeeping Services (approved 2-12) failed to indicate the following:</p> <p>a. IC committee review and approval b. a specific process for OR cleaning to prevent contamination of previously disinfected surfaces c. a provision ensuring that all high-touch surfaces were cleaned and/or disinfected</p> <p>2. During an interview on 12-11-13 at 1700 hours, staff A1 confirmed that the policy/procedure lacked the indicated provisions.</p>	S000428	The Housekeeping policy was updated to provide a description of a specific process for OR cleaning to prevent contamination of previously disinfected surfaces and a provision ensuring all high-touch surfaces are cleaned and disinfected. The Infection Control committee will review and approve changes at the next meeting. The surgery manager will ensure that quarterly meetings take place and document meeting minutes and present them to governing board. The surgery manager will orient housekeepers on policy changes and periodically observe the cleaning of the facility. Please see Policy 11.01.	01/10/2014	

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S000440	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(vii)</p> <p>The infection control committee responsibilities must include, but not be limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases. Based on policy and procedure review, document review, personnel file review, and interview, the infection control committee failed to implement its policies related to: employee immunization status (staff N1, N4, and N6) and exposure from needle/blade sticks (staff N4 and N13) .</p> <p>Findings:</p> <p>1. Review of the policy and procedure "Blood Borne Pathogen Testing of Patients and Employees", policy number 10.15, with a revised date of 2/10, indicated:</p> <p>a. under "Policy", it reads: "In the event of a blood borne pathogen exposure, serologic testing is needed on the source person and the recipient for adequate medical treatment..."</p>	S000440	<p>3. Staff member N1 was sent for Varicella titer to be drawn-awaiting results; Staff member N4 was sent to have Rubella and Rubeola titers drawn-awaiting results; Staff member N6 was sent for Varicella titer to be drawn-awaiting results. 5. Staff members N13 and N4 signed a declination form for lab testing for Hepatitis A, B, and C, or for HIV after a "oasis blade" stick incident. The surgery manager counseled the employees concerning exposure. Both patients involved in the incidents were tested per policy and the results were negative. Employees N13 and N4 were notified of test results. The surgery manager will ensure that employees are offered Hepatitis A, B, & C and HIV</p>	01/10/2014	

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	<p>2. Review of the policy and procedure "Blood Borne Disease Exposure Control Plan", policy number 10.14, with a revised date of 1/11, indicated:</p> <p>a. under "Practices & Procedures", it reads: "1. Employment Physical Examination A. An initial health physical, will be completed by a physician upon hire of each staff member. Proof of communicable diseases may be accepted if the employee has a copy from another health institution's records or from staff member's primary care physician of said communicable diseases. See attached Health Care Personnel Vaccination Recommendations for further information. These recommendations will be a guide as to what is needed for each staff member on hire." (* The attached document indicated a CDC (centers for disease control and prevention) document that indicated immunity to communicable diseases (Rubella, Rubeola, and Varicella) for HCWs (healthcare workers) would include: physician documentation of having had the disease, or a titer showing immunity to the disease, or the documentation of immunization for the communicable disease)</p> <p>b. under section "VI. Reporting and Processing Exposure to Infectious Disease", it reads: "...C....2. The Surgery</p>		<p>testing after exposure to blood or body fluids. The surgery manager will counsel employees concerning exposure.</p>	

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	<p>Manager will counsel employee/physician concerning exposure and the employee/physician will be requested to be tested and consent obtained if testing is to take place. If employee/physician declines, a declination form should be completed..."</p> <p>3. review of employee medical records indicated: a. staff member N1 was hired 10/22/12 and had a self reported document stating the employee had previously had chickenpox b. staff member N4 was hired in 2010 and lacked any information related to rubella or rubeola immunity c. staff member N6 was hired 5/2/13 and lacked documentation related to varicella immunity</p> <p>4. interview with staff member #60, the RN (registered nurse) surgery manager, at 2:50 PM on 12/11/13 and 10:15 AM on 12/12/13, indicated: a. it was unknown that a self reported immunity to Varicella was not acceptable b. it was unclear why there was no rubella or rubeola information for staff member N4, nor Varicella information for staff member N6</p> <p>5. review of incident reports for the last 6 months indicated:</p>				

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	<p>a. staff member N13 had a left thumb stick from an "oasis blade" on 6/4/13 and lacked documentation of having had lab tests for Hepatitis A, B, and C, or for HIV (Human Immunodeficiency Virus), or a declination form indicating the staff member refused this testing</p> <p>b. staff member N4 had a finger stick with an "oasis blade" on 8/20/13 and lacked documentation of having had lab tests for Hepatitis A, B, and C, or for HIV (Human Immunodeficiency Virus), or a declination form indicating the staff member refused this testing</p>			

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S000466	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(3)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not limited to, the following:</p> <p>(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.</p> <p>(B) Results of biological indicators used in testing the sterilizing processes.</p> <p>Based on document review and interview, the infection control committee failed to ensure the periodic evaluation of biological indicators and sterilizing processes.</p> <p>Findings: 1. Review of the Governing Board (Quality Assurance) committee meetings of 1/2/13 and 7/22/13, indicated that sterilization processes and biological indicators are not reviewed/discussed at the meetings for the group assigned to represent the infection control committee for the facility</p>	S000466	The surgery manager will ensure that the records of thermometers and/or daily record of the sterilizing cycle and periodic evaluation of sterilization processes and results of biological indicators will be discussed at the quarterly governing board/QA/IC meeting and documented in the meeting minutes as per policy.	01/12/2014			

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	<p>2. interview with staff member #60, the RN (registered nurse) and surgery center manager, at 2:15 PM on 12/11/13, indicated:</p> <p>a. if there were any errors or discrepancies with biological indicators, then these would be discussed/presented at meetings</p> <p>b. currently, there is no documentation of periodic evaluation of sterilization processes or biological indicators by the infection control committee/governing board</p>			

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S000526	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed. Based on personnel file review and interview, the facility failed to document the skills competencies for waived lab testing performed by nursing staff.</p> <p>Findings:</p> <ol style="list-style-type: none"> review of personnel files indicated that orientation and annual forms titled "Employee Proficiency Checklist, had an item under "Equipment Skill Checklist" that is numbered: "41 Glucometer", but lacks specific skills that are checked off for staff to indicate their skills competencies related to glucometer checks for patients staff member N5 was hired 7/23/13 and lacks completion of the "Employee Proficiency Checklist" interview with staff member #60, the RN (registered nurse) surgery center manager, at 3:15 PM on 12/11/13, indicated: <ol style="list-style-type: none"> there is no actual checklist that staff are monitored by upon hire and annually 	S000526	All staff will attend an in-service and complete a competency regarding the glucometer. This will be done upon hire and annually as per policy. The surgery manager will conduct in-services and document the skills competency annually and as needed. The Employee Proficiency checklist will be completed by the surgery manager for employee N5. The surgery manager will ensure that Employee Proficiency checklists are completed on each new employee hired as per policy. The Eye Surgical Center of Fort Wayne has added Policy 9.03-Pregnancy testing. The center employees will perform pregnancy testing on females per policy. Staff will attend an in-service given by the surgery manager and complete a competency upon hire and on an annual basis. Please see attached Glucometer check-off and Policy 9.03.	01/09/2014			

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	<p>in relation to skills competencies for glucometer checks</p> <p>b. facility policy indicates that patients may range in age from 3 years of age and up, but the facility lacks a policy regarding the performance of pregnancy tests prior to a surgical procedure for the safety of the patient/fetus</p>			

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S000732	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p> <p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially. Based upon document review and interview, the medical staff failed to document the review and approval its bylaws, rules and regulations at least triennially.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation indicating the most recent medical staff approval of the medical staff bylaws, rules and regulations and none was provided prior to exit. The Bylaws of the Medical Staff of the Eye Surgical Center of Fort Wayne lacked a provision for periodic approval by the medical staff at least triennially. The Addendum to the Policy and Procedure Manual of the Eye Surgery Center of Fort Wayne dated 2-22-11 failed to indicate that the medical staff bylaws were reviewed and approved by the medical staff or governing board. 	S000732	The Medical Staff bylaws have been amended to show that the bylaws will be reviewed and approved on a triennial and as needed basis. The Medical Staff will review and approve said bylaws at their next meeting. The surgery manager and chief executive will ensure that medical staff meetings are held quarterly and meetings are documented. Please see attached Policy 2.01.	01/12/2014			

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	4. During an interview on 12-12-13 at 1200 hours, medical director A2 confirmed that no documentation of medical staff approval of the center medical staff bylaws, rules and regulations was available.			

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S000904	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)(1)</p> <p>(a) Patient care services must require the following:</p> <p>(1) That the patient care services rendered are reviewed and analyzed at regular meetings of patient care personnel and used as a basis for evaluating the quality of services provided.</p> <p>Based on policy and procedure review, document review, and staff interview, the surgery manager failed to implement the facility policies regarding monthly staff meetings in either 2012 or 2013 and follow up patient phone calls for 5 patients (pts. #1, #4, #5, #10 and #13).</p> <p>Findings:</p> <p>1. review of the policy and procedure "Staff Meetings", policy number 5.03, with a last revised date of 1/10, indicated:</p> <p>a. under "Policy", it reads: "Meetings of center personnel shall be conducted on a minimum monthly basis for the purpose of communication which may include the following topics: reviewing patient care services..."</p> <p>2. review of the staff meeting minutes binder indicated that only two meetings were held in 2012, on 4/4/12 and 10/2/12, and that none were documented for 2013</p>	S000904	The Eye Surgical Center of Fort Wayne will begin holding monthly staff meetings to discuss any new business and review policy and procedures. The staff will be given an inservice to review the policy on completing post-op phone calls. The surgery manager will ensure that meetings are held, documented and reported.	01/10/2014	

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	<p>3. interview with staff member #60, the RN (registered nurse) surgery manager, at 12:30 PM on 12/12/13, indicted that no staff meetings have occurred as required by facility policy</p> <p>4. review of the policy and procedure "Post-Operative Telephone Call", policy number 5.37, with a last revised date of 1/11, indicated: a. under "Practices & Procedures", it reads: "...4. In the event the patient is not contacted on the initial attempt, one additional attempt will be made..."</p> <p>5. review of patient medical records indicated that patients #1, #4, #5, #10 and #13 only received one follow up phone call in which the staff member noted "left message" on the form in the patient's chart</p> <p>6. interview with staff member #60 at 2:15 PM on 12/11/13 indicated this staff member was unaware that there was a policy that required a second attempt for follow up with a patient if there was no answer on the first attempt</p>			

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S001026	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(E)(i)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:</p> <p>(i) Drug cabinets must be accessible only to authorized personnel.</p> <p>Based on policy and procedure review, observation, and staff interview, the facility failed to ensure that medications were accessible to only authorized personnel in two locations.</p> <p>Findings: 1. review of the policy and procedure "Pharmaceutical Services", policy number 8.01, with a last revised date of 2/10, indicated: a. under "Policy", it reads: "Pharmaceutical supplies and services shall be maintained and controlled in accordance with acceptable ethical and professional practices and all legal requirements."</p>	S001026	The refrigerator with several multi-dose vials of IV medications is now kept locked unless surgery is being performed. It is unlocked during the surgery day and locked at the conclusion of surgery. The IV medications Mannitol and Zofran have been removed from the unlocked cart in surgery room A. They are kept in a locked cabinet. Policy 8.01 has been changed to reflect that only authorized personnel should have access to medications. The surgery manager will ensure that the refrigerator remains locked during non-surgery days and that the policy is followed. Please see attached Policy 8.01.	12/31/2013			

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	<p>2. at 4:00 PM on 12/11/13 while on tour of the "back hallway" of the surgical area (outside the OR suites), it was observed that an unlocked refrigerator contained several multidose vials of IV medications (in a basket with one of the surgeon's names printed on a post it note)</p> <p>3. while on tour of the surgical area at 4:15 PM on 12/11/13, it was observed in OR (operating room) "A" that a cart was unlocked and contained IV (intravenous) medications: Mannitol--2 vials 50 cc each, and Zofran--2 vials 10 cc each</p> <p>4. interview with staff member #60, the RN (registered nurse) surgery manager at 4:15 PM on 12/11/13 indicated:</p> <p>a. both areas with IV medications were unsecured and accessible to the contracted housekeeping staff and other unauthorized personnel</p> <p>b. the policy (8.01) fails to specify that only authorized personnel should have access to medications</p>			

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S001146	<p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on policy and procedure review, manufacturer's booklet review/recommendations, observation, and interview, the facility failed to ensure that no condition was created that might create a hazard to patients in regard to the possibility of incorrect blood sugar checks and failed to maintain its equipment which resulted in a potential hazard to surgical patients at the center.</p> <p>Findings:</p> <p>1. Review of the policy and procedure "Blood Glucose Level Testing", policy number 9.02, with a last reviewed date of 1/11, indicated:</p> <p>a. the policy does not address monitoring and dating the control solutions and test strips with expiration dates</p>	S001146	The glucose control solutions that had expired on 11/27/13 have been disposed of and new solutions were opened and marked with the open date and expiration date as indicated in the policy. The test strips have also been labeled with the open date and expiration date. The staff has been given an inservice regarding this policy. The Surgery Manager will ensure that the policy is followed by the staff. Matt Klotz-heating and air repairman has been contacted and will be in 01/06/2014 to repair the round ceiling diffuser in surgery room A. The Surgery manager will ensure that the diffuser is repaired and will monitor for any other repairs needed.	01/06/2014			

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	<p>2. review of the log book kept in the pre/post op area of the facility at 4:15 PM on 12/11/13, indicated:</p> <p>a. page 40 of the True Result Quality Assurance/Quality Control Manual for the glucometer, read:</p> <p>1. "...Write the date first opened on Test Strip vial label. Discard vial and unused Test Strips if either EXP (expiration) date printed on Test Strip vial label or 4 months after date written on vial label has passed..."</p> <p>2. "...Write the date first opened on Control bottle label. Discard bottle if either EXP date printed on bottle label or 3 months after date written on bottle label has passed..."</p> <p>b. the log book kept by surgery personnel indicated the control solutions had been opened 8/27/13 and expired on 11/27/13</p> <p>3. while on tour of the pre/post op area at 4:30 PM on 12/11/13, the following was observed:</p> <p>a. two bottles (level 1 and level 2) of control solution were not marked with an opened date, or a 3 month expiration date</p> <p>b. the test strips were not marked with an opened date, or a 4 month expiration date</p> <p>4. interview with staff member #60, the RN (registered nurse) and surgery manager, at 4:35 PM on 12/11/13</p>						

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	<p>indicated:</p> <p>a. the control solutions, per the log book, had expired 11/27/13</p> <p>b. the control solutions and test strips were not marked with opened and expiration dates, as facility policy requires</p> <p>5. The policy/procedure Maintenance Services (approved 2-12) indicated the following: " The facilities and equipment of the center will be maintained in a manner so as to assure their functional reliability and the safety of patients and personnel. "</p> <p>6. During a tour on 12-11-13 at 1610 hours, the following condition was observed in the operating room A: the outer edge of a 36 " round ceiling diffuser was observed to be hanging down approximately ½ " below the ceiling surface plane. The ½ " ceiling breach into the operating room presented a transmission risk for surgical site contamination from the uncontrolled environment above the surgery ceiling.</p> <p>7. During an interview on 12-11-13 at 1610 hours, staff A1 confirmed that the hanging ceiling diffuser was a potential hazard to surgical patients and would be corrected as soon as possible.</p>				

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S001170	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iv)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p> <p>Based on document review, observation and interview, the center failed to maintain its policy/procedure and emergency equipment as recommended by the manufacturer to ensure the equipment was fully operational for patient use if needed.</p> <p>Findings:</p> <p>1. The Hewlitt-Packard M1722B Codemaster XL+ Defibrillator/Monitor (2000) User ' s Guide indicated the following: " Regularly perform a test routine incorporating the following</p>	S001170	The policy and checklist has been amended to include daily visual inspection of patient cables, AC power cord, paddles, and controls for wear. The staff has been given an inservice regarding changes. The surgery manager will ensure that the checklist is completed daily as per policy. The center defibrillator HP M1722B was checked by Bio-med and he was unable to fix the broken strain relief. A new defibrillator was ordered and we are awaiting the arrival. The Surgery center has an AED to use until the defibrillator arrives. The surgery manager will give an	01/06/2014

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	<p>checks along with a visual inspection of all cables, paddles, and controls ...Every Day ...visually check the AC power cord for wear. Visually check the patient cables, paddles cables, and electrode adaptor cables for wear, insulation nicks, and other damage ... "</p> <p>2. The policy/procedure Checklist For Crash Cart and Critical Equipment (approved 2-12) and emergency equipment checklist failed to indicate a provision to perform a visual inspection of all cables and paddles for wear and damage in accordance with the manufacturer recommendations.</p> <p>3. During a tour on 12-11-13 at 1555 hours in the restricted surgical area of the center, the center defibrillator HP M1722B was observed on the top of the Crash Cart with the following condition: a broken strain relief on the terminal wiring connection from the defibrillator paddles at the union with the connection block inserted into the handle and housing of the defibrillator. The wiring connection and strain relief moved freely in and out of the connection block approximately ¼ " rather than being fully secured and immovable within the connection block.</p> <p>4. During an interview on 12-11-13 at</p>		<p>inservice to the employees on the operation of new defibrillator when it arrives. Please see attached Policy 5.41 and Crash Cart Check-list.</p>				

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	1610 hours, staff A1 confirmed that the daily defibrillator checks were not being performed according to the manufacturer's recommendations.				

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S001180	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.</p> <p>Based on document review and interview, the center lacked documentation of an organized safety management program that included a review of safety functions by a committee appointed by the chief executive officer (CEO) and included representatives from administration and patient care services.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation of a safety program including committee meeting minutes and none was provided prior to exit. The policy/procedure Safety Management (approved 1-12) failed to indicate that the appointment of safety committee members was the responsibility of the CEO. The policy/procedure indicated that the 	S001180	The Safety committee will conduct quarterly meetings and document meeting minutes, listing the attendees of the meeting. The surgery manager and Safety officer will ensure that meetings are held and documented per policy.	01/12/2014	

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	<p>committee will meet at least quarterly and failed to indicate if the meeting was conducted separately or as a sub-committee of the Quality Improvement Committee (QIC).</p> <p>3. The QIC minutes dated 12-27-12, 4-10-13, and 7-22-13 failed to indicate the names of any members who attended the meetings and failed to indicate a safety committee section heading, function or safety committee discussion or action if incorporated within the QIC meeting.</p> <p>4. During an interview on 12-11-13 at 1520 hours, staff A1 confirmed that the QIC minutes lacked documentation of the safety sub-committee membership or a quarterly review of safety functions.</p>			

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S001182	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(2)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Based upon document review and interview, the safety management program lacked an ongoing, center wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Findings:</p> <p>1. On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation of safety committee meetings including the process evaluate and review information about safety practices and hazards and none was provided prior to exit.</p> <p>2. The QIC minutes dated 12-27-12, 4-10-13, and 7-22-13 failed to indicate that an incident report dated 6-14-13 or a quarterly fire drill performed on 2-21-13 and 4-02-13 were discussed or reviewed</p>	S001182	The surgery manager and Safety Officer will ensure quarterly meetings are held and documented per facility policy. Quarterly fire drills and any incident reports will be discussed at meetings and reported to governing board. Please see attached ASC Risk Management checklist. This checklist is completed monthly by the Safety Officer to evaluate and collect information about safety issues and practices. This will be discussed at quarterly meetings.	01/10/2014	

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	<p>including any safety sub-committee recommendations if incorporated within the QIC meeting.</p> <p>3. During an interview on 12-11-13 at 1520 hours, staff A1 confirmed that the safety management program failed to document an ongoing process for evaluating and collecting information about safety issues and practices.</p>			

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S001198	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the center failed to follow its policy/procedure regarding emergency preparedness and perform periodic disaster and emergency preparedness drills for 4 of 4 drills in 2013.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Emergency Operations and Disaster Plan (approved 2-12) indicated the following: " The ASC will conduct one (1) drill each calendar quarter of the internal emergency and disaster preparedness plan. " On 12-10-13 at 1030 hours, staff A1 was requested to provide documentation of disaster drills performed in 2013 and none was provided prior to exit. During an interview on 12-11-13 at 1500 hours, staff A1 confirmed that no 	S001198	The surgery manager and Safety officer will ensure that quarterly disaster and emergency preparedness drills are conducted, documented, and reported to the governing board per policy.	01/09/2014	

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	disaster drill documentation was available.			