

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001090	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____	X3) DATE SURVEY COMPLETED 10/28/2015
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NAME OF PROVIDER OR SUPPLIER ALLIED PHYSICIANS SURGERY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 53990 CARMICHAEL DR STE 100 SOUTH BEND, IN 46635
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Q 0000 Bldg. 00	The visit was for a re-certification survey. Facility Number: 010984 Survey Date: 10-26/28-15 QA: cjl 12/02/15	Q 0000		
Q 0082 Bldg. 00	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. Based on document review and interview, the center failed to ensure its patient transfers were evaluated and	O 0082	A separate line item will be added to the QI Meeting Minutes listing "Transfers and ER Visits". All information pertaining to any	01/19/2016

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>reviewed through its medical quality improvement committee (MQIC) for 1 transfer identified in 2015 program documentation.</p> <p>Findings include:</p> <ol style="list-style-type: none"> The policy/procedure Medical Quality Improvement (QI) Risk Management Program (approved 2-15) indicated an Adverse Event Report would be completed for all risk management issues and indicated the MQIC committee would evaluate all patient transfers. The 1st quarter 2015 MQIC minutes dated 4-21-15 indicated the following: The QI report was presented for the physician review. The report was not read in its entirety and only areas requiring discussion were covered. The MQIC minutes failed to indicate a committee discussion, recommendation, or action regarding the one hospital transfer identified in the attached Quality Improvement Report during the committee meeting. During an interview on 10-28-15 at 1100 hours, staff A5, the quality coordinator, confirmed that the April, 2015 MQIC minutes failed to indicate documentation of committee member discussion or recommendations 		<p>transfers or ER visits will be contained in the Quality Improvement (QI) meeting packet to be reviewed by the QI Committee during the meeting. To insure ongoing compliance, the QI Coordinator will be provided information on all Transfers and ER visits at the time they occur so they can be tracked and added to the QI Meeting Agenda under the topic "Risk Management". The QI Coordinator will be responsible for preparing the QI Committee Meeting packet and presenting to the Executive Director for review and approval prior to each quarterly QI meeting. This process will be implemented with the next scheduled Medical Quality Improvement Committee meeting to be held on January 19, 2016.</p>	

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Q 0141 Bldg. 00	<p>associated with a review of the patient transfer reported in the QI report and no other documentation was provided prior to exit.</p> <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 document review and interview, the facility failed to ensure that patient care policies related to medication administration were followed for 1 of 1 patient with post anesthesia orders written by physician #66, patient #8.</p> <p>Findings Include: 1. Review of the policy Medication Guidelines - Administration and Storage, no policy number, last approved 2/3/15, indicated that medication administration will include the following checks immediately before giving the drug: the right medication, in the right dose, to the right person, by the right route, at the right time. 2. Review of medical records indicated that orders written by anesthesiologist #66 for pt. #8 on 10/3/14 were for</p>	Q 0141	<p>Medication Guidelines-Administration and Storage CL 9.073.12 policy and procedure will be revised as follows: "All persons who administer medications may divert pain/nausea medication and the patient may receive a replacement of lesser or not strength", (per language taken from AORN standard RP-Medication Safety,X.a.2). Revised policy will reflect current medication practices. Clinical Director will be responsible for implementation and education of all staff. Annual review of all policies and procedures will be completed by the Governing Body. Completion date of 1/11/16. *** 1/12/16 - CORRECTION UPDATE *** APSC has a policy titled, "Medication Guidelines –Administration and Storage" CL 9.073.12 to ensure the 5</p>	01/25/2016

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Q 0162 Bldg. 00	<p>Fentanyl 50 mcg (micrograms) every 2 to 5 minutes as needed for pain with a maximum of 200 mcg., and that nursing noted giving 25 mcg at 1:22 PM, and again at 1:27 PM, on 10/3/14.</p> <p>3. At 2:45 PM on 10/27/15, interview with staff member #50, the executive director, confirmed that pt. #8 received 25 mcg of Fentanyl two times, when the order was for 50 mcg., thus not per physician orders.</p> <p>416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:</p> <p>(1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the</p>		<p>rights of medication administration are followed. The policy intended guidelines were not properly carried out by staff members in regard to proper dosing of medications to patients.</p> <p>Reeducation to all perioperative RN's by the Clinical Director and Perioperative Charge Nurse will begin immediately and completed by 1/18/16. A letter from the Medical Director will be sent to all credentialed anesthesiologist by 1/15/16 to reinforce the necessity of dose specific medication orders. Random chart audits will be completed from 2/1/16 thru 2/29/16 to ensure proper compliance. Further reviews will be completed during the 2nd quarter nursing chart audit. Completion date of 1/25/16</p>	

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	<p>governing body.</p> <p>(5) Any allergies and abnormal drug reactions.</p> <p>(6) Entries related to anesthesia administration.</p> <p>(7) Documentation of properly executed informed patient consent.</p> <p>(8) Discharge diagnosis.</p> <p>Based on document review and interview, the medical staff failed to follow its rules and regulations related to history and physicals (H & Ps) for 1 of 1 patient for physician #61, patient #4, and related to operative notes for 1 of 1 patients for physician #64, patient #3.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> Review of the medical staff rules and regulations approved on 8/18/15, indicated on page 4 under section 8., Medical Records: c. upon admission, each patient must have a comprehensive medical evaluation completed by a privileged member of the medical staff. The original history and physical must be no more than 30 days before the date of the scheduled procedure to be eligible to be updated. Review of patient medical records indicated that patient #4 had an office H & P dated 9/11/15 with surgery on 10/27/15. At 11:50 AM on 10/28/15, interview 	O 0162	<p>Medical staff will be required to review rules and regulations associated with the standard concerning updated H & P's. A letter from the Medical Director will be sent to all physicians along with the rules and regulations pertaining to this topic by 1/8/16. Pre-operative staff will be re-educated on the requirements of the H & P by the Clinical Director by 1/11/16. For all cases they will verify H & P date is within 30 days of the procedure. If outdated by the 30 day criteria, a comprehensive H & P will be presented for completion by the Surgeon prior to patient surgical procedure or case will be cancelled. This topic will be presented at the next scheduled Medical Quality Improvement (QI) Committee meeting on 1/19/16 for discussion and any further input. Medical staff will be required to review rules and regulations associated with the standard concerning Operative Report written or dictated immediately after procedure. A letter from the Medical Director will be sent to all physicians along with the rules and regulations pertaining to this topic by 1/8/16.</p>	01/08/2016	

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	<p>with staff member #52, the clinical director, confirmed that the H & P for patient #4 was greater than 30 days, and that the brief H & P, on the form titled Indications for Surgery/Surgeon's Admitting Notes, was not complete enough to consider it the brief H & P that can be completed on the day of surgery. No other documentation was provided prior to exit.</p> <p>4. Review of the medical staff rules and regulations approved on 8/18/15, indicated on page 4 under section 8., a standard operative note by the operating physician...is to be written or dictated immediately after the procedure.</p> <p>5. Review of medical records indicated patient #3 had surgery on 6/24/15 and had an area checked at the bottom of form APSC-127 (Allied Physicians Surgery Center) indicating that an operative report was dictated immediately post op. The rest of the area was blank and the dictated report was dated 6/25/15.</p> <p>6. At 11:50 AM on 10/28/15, interview with staff member #52, the clinical director, indicated that if the brief post op area on the bottom of form APSC-127 is completed, the physicians can dictate their op reports after the day of surgery.</p>		<p>Medical Records will verify dictation postoperatively was completed by either written post-operative note or dictation for compliance with policy. Any non-compliance will be reported to the Medical Director for immediate follow-up with non-compliant physician. If not completed within 24 hours, physician will be suspended until complete. This topic will be presented at the next scheduled Medical Quality Improvement (QI) Committee meeting on 1/19/16 and process will be discussed and evaluated. No changes in rules and regulations at this time will be made. Plan of action is enforcement of current rules and regulations.</p>	

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Q 0203 Bldg. 00	<p>Physician #64 did not complete the bottom of the form and checked that they had dictated their report immediately following surgery, but the dictated report indicates this occurred on 6/25/15, thus not per medical staff rules and regulations. No other documentation was provided prior to exit.</p> <p>416.49(b)(1) RADIOLOGIC SERVICES [Radiologic services...]</p> <p>must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter. Based on document review and interview, the center failed to ensure that all female patients of childbearing age were screened to minimize the potential for exposing a fetus to ionizing radiation.</p> <p>Findings:</p> <p>1. Review of the policy/procedure Radiology, Radiation Safety (approved 2-15) indicated the following: Measures to protect patients from direct and indirect radiation exposure should be documented on the peri-operative or intra-operative nursing record. The policy/procedure failed to indicate the specific measures to be taken and documented.</p>	O 0203	<p>Pre-Operative Evaluation of Patients by the Center's Pre-Operative Nurses CL 9.096.04 and Radiology, Radiation Safety CL 9.098.04 policy and procedures will be revised to include "urine HCG will be obtained on all females who have started their menses through one year post menopause" (exceptions post hysterectomy and tubal ligation patients). Education of new testing requirement for patients will be conducted for all staff members. This will insure that all female patients of child bearing age were screened to minimize the potential for exposing a fetus to ionizing radiation. Clinical Director and Perioperative Charge Nurse will educate all staff members to policy revisions</p>	01/11/2016

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Q 0204 Bldg. 00	<p>2. Review of the policy/procedure Pre-Operative Evaluation of Patients, by Center's Pre-op Nurses (approved 2-15) indicated the following: Urine [human chorionic gonadotropin] HCG will be run as ordered or as a nursing judgment when there is a suspicion of pregnancy. (sic) Late menstrual cycle or there is no use of birth control. The policy/procedure failed to ensure that a urine pregnancy test was performed on all potentially pregnant female patients of childbearing age before any exposure to ionizing radiation would occur.</p> <p>3. During an interview on 10-26-15 at 1520 hours, staff A1, the administrator, confirmed that the policy/procedures failed to ensure a urine pregnancy test would be performed on all female patients with a potential for being pregnant before the start of any surgical procedure utilizing ionizing radiation.</p> <p>416.49(b)(2) RADIOLOGIC SERVICES (2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section. Based upon document review and interview, the center failed to ensure that</p>	O 0204	<p>and new testing requirements. Completion date of 1/11/16.</p> <p>A Radiologist will be appointed by the Governing Body to review all Radiology policy and procedures,</p>	01/19/2016

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	<p>its radiology services were supervised by a radiologist or radiation oncologist appointed to the medical staff in accordance with State law 410 IAC 15-2.5-8(c)(1).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Indiana Administrative Code 410 IAC 15-2.5-8(c)(1) indicated the following: Radiology services must be supervised by a radiologist or radiation oncologist. 2. On 10-26-15 at 1030 hours, staff A1, the administrator, was requested to provide documentation indicating that the center radiologic services were supervised by a qualified individual appointed by the governing board in accordance with State law and none was provided prior to exit. 3. Review of 2014 and 2015 radiation dosimetry reports, radiology equipment calibration reports, radiology safety policy/procedures, and lead apron shielding inspection reports failed to indicate that a review by a radiologist had been performed. 4. During an interview on 10-28-15 at 1035 hours, staff A3, the clinical director confirmed that a qualified medical physicist was supervising the radiologic 		<p>quarterly dosimetry reports, regular equipment inspections and hazard corrections, review of lead apron shielding inspection, review of facility state licensure and all radiologic technologist's licenses. A Letter of Agreement will be drafted and signed by Radiologist and the Governing Body and will be reviewed on an annual basis to insure that all requirements are being met. The QI Coordinator will provide all data to the Radiologist for review on an annual basis. The results of this review will be included in the first QI Committee meeting following this annual review. Letter of Agreement will be prepared and signatures obtained by January 19, 2016.</p>		

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Q 0221 Bldg. 00	<p>services provided at the center and confirmed that the radiologic services lacked documentation of supervision by a radiologist.</p> <p>416.50(a) NOTICE OF RIGHTS An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>Based on document review and interview, the center failed to assure the notice of patient rights provided to a patient, patient representative or surrogate included 11 of 14 required elements and failed to assure the medical record (MR) indicated the notice of rights was provided prior to the procedure for 10 of 10 MR reviewed (patient #s 1, 2, 3, 4, 5, 6, 7, 8, 9 & 10).</p> <p>Findings:</p> <p>1. The written notice of patient rights provided to patients in the registration</p>	O 0221	<p>We have drafted a new Patient Rights and Responsibilities to be offered to each patient, which will include revised language covering all the required elements. Each patient will sign a form acknowledging receipt of this document. This will be part of the "Acknowledgement of Notice of Privacy Practices, Patient Rights and Responsibilities, Advance Directive Policy and Physician Ownership Disclosure" form. This form will be placed in the medical record of each patient. Staff will be educated by the QI Coordinator and the Business Office Manager on</p>	01/11/2016

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	<p>area failed to indicate the following:</p> <p>A. notice of the right to receive verbal and written notice of the patient's rights in advance of the procedure, in a language and manner that the patient or the patient's representative understands.</p> <p>B. notice of the address of the Indiana State Department of Health for mailing a complaint: Indiana State Department of Health, Division of Long term Care, 2 North Meridian, Indianapolis, Indiana 46204, telephone # 1-800-246-8909 and the web site of the Office of the Medicare Beneficiary Ombudsman (https://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html)</p> <p>C. notice of the physicians with a financial interest or ownership in the ASC center.</p> <p>D. notice of the availability of a copy of the State advanced directive forms upon request.</p> <p>E. notice of how to submit a complaint or grievance.</p> <p>F. notice the center will respond immediately to all grievances related to (but not limited to): mistreatment, neglect, verbal, mental, sexual and/or physical abuse or any other serious allegations of harm, all such grievances will be promptly investigated, and substantiated allegations will be reported to either the State or local authority, or</p>		<p>implementation of this new form. Business Office Manager will review on an ongoing basis with staff to insure compliance. Use of new form will begin on 1/11/16.</p>	

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	<p>both.</p> <p>G. notice that patients may exercise their rights without being subjected to discrimination or reprisal</p> <p>H. notice of the right to submit grievances regarding treatment or care that is (or fails to be) furnished.</p> <p>I. notice that the rights of the patient may be exercised by the person appointed under State law to act on the patient's behalf when a patient is adjudged incompetent, and by any legal representative designated by the patient when a State court has not adjudged a patient incompetent.</p> <p>J. notice of the right to receive care in a safe setting.</p> <p>K. notice of the right to be free of all forms of abuse, neglect, or harassment from staff, other patients, or visitors.</p> <p>2. During an interview on 10-27-15 at 1435 hours, staff A1, the administrator, and A5, the quality coordinator, confirmed that the posted information lacked the indicated requirements.</p> <p>3. Review of the MR document titled Acknowledgement of Notice of Privacy Practices for patient #s 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 failed to indicate that the notice of rights was provided to each patient or patient's representative (at the time prior to the procedure when the</p>				

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Q 0222 Bldg. 00	<p>notice of patent rights, notice of privacy practices, and notice of the center policy on Advance Directives was provided).</p> <p>4. During an interview on 10-27-15 at 1435 hours, staff A1, the administrator, and staff A5, the quality coordinator confirmed that the MR for patient #'s 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 failed to indicate the notice of patient rights was provided to each patient and no additional documentation was provided prior to exit.</p> <p>416.50(a)(1)(i) NOTICE OF RIGHTS - POSTING (1)[...] In addition, the ASC must -</p> <p>(i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>Based on observation and interview, the center failed to ensure that the posted patient rights notice included 11 of 14 required elements.</p> <p>Findings:</p>	O 0222	Revised Patient Rights and Responsibilities will be prominently posted in the Lobby of Allied Physicians Surgery Center. QI Coordinator will be responsible for completion of this task by 1/11/16.	01/11/2016

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	<p>1. The patient rights document posted in the registration area failed to indicate the following:</p> <p>A. notice of the right to receive verbal and written notice of the patient's rights in advance of the procedure, in a language and manner that the patient or the patient's representative understands.</p> <p>B. notice of the address of the Indiana State Department of Health for mailing a complaint: Indiana State Department of Health, Division of Long term Care, 2 North Meridian, Indianapolis, Indiana 46204, telephone # 1-800-246-8909 and the web site of the Office of the Medicare Beneficiary Ombudsman (https://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html)</p> <p>C. notice of the physicians with a financial interest or ownership in the ASC center.</p> <p>D. notice of the availability of a copy of the State advanced directive forms upon request.</p> <p>E. notice of how to submit a complaint or grievance.</p> <p>F. notice the center will respond immediately to all grievances related to (but not limited to): mistreatment, neglect, verbal, mental, sexual and/or physical abuse or any other serious allegations of harm. All such grievances will be promptly investigated and</p>			

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Q 0224 Bldg. 00	<p>substantiated allegations will be reported to either the State or local authority, or both.</p> <p>G. notice that patients may exercise their rights without being subjected to discrimination or reprisal</p> <p>H. notice of the right to submit grievances regarding treatment or care that is (or fails to be) furnished.</p> <p>I. notice that the rights of the patient may be exercised by the person appointed under State law to act on the patient's behalf when a patient is adjudged incompetent, and by any legal representative designated by the patient when a State court has not adjudged a patient incompetent.</p> <p>J. notice of the right to receive care in a safe setting.</p> <p>K. notice of the right to be free of all forms of abuse, neglect, or harassment from staff, other patients, or visitors.</p> <p>2. During an interview on 10-27-15 at 1435 hours, staff A1, the administrator, and A5, the quality coordinator, confirmed that the posted information lacked the indicated requirements.</p> <p>416.50(c)(1)(2)(3) ADVANCED DIRECTIVES The ASC must comply with the following requirements:</p>			

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	<p>(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.</p> <p>(2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.</p> <p>(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.</p> <p>Based on document review, observation and interview, the facility failed to ensure that it was documented in a prominent part of the patient medical record whether or not the individual had executed an advance directive for 10 of 10 MR (medical records) reviewed, MR #1, #2, #3, #4, #5, #6, #7, #8, #9 and #10 and failed to assure that a copy of the Indiana State Advanced Directives brochure was provided to patients if requested.</p> <p>Findings Include: 1. Review of the Advanced Directives/Living Will policy, no policy number, effective date of 3/6/12, and last approved on 2/3/15, indicated there was nothing in the policy related to the need for documentation in the medical record whether or not the patient had an advance</p>	O 0224	We are revising our Advance Directive / Living Will AD 3.030.04 policy to state that during Pre-Op assessment it will be noted on the Pre-Operative record if the patient has executed an Advance Directive and if the facility has been provided a copy. Our Pre-Operative record is also being revised to reflect the above. In addition, upon Registration each patient will be given a copy of our Advance Directive policy. They will also be made aware of the Indiana State Board of Health Advance Directive brochure and given information on how to obtain this brochure. During their pre-op assessment it will be documented whether the patient has executed an Advance Directive and if they have provided us a copy. If a copy has been received, it will be placed in the patient chart. QI	01/18/2016

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	<p>directive.</p> <p>2. Review of the medical records for patients #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 indicated there was nothing noted in the medical records indicating whether or not the patient had executed an advance directive.</p> <p>3. At 9:25 AM on 10/27/15, interview with staff member #51, the administrative assistant, confirmed that the patient medical records, as listed above, lacked indication of whether or not the patient had executed an advance directive, and no other documentation was provided prior to exit.</p> <p>4. Review of the policy/procedure Patient Rights (approved 2-15) and Advanced Directives/Living Will (approved 2-15) failed to indicate that the center would provide a copy of the State Advanced Directives brochure to the patient or the patient's representative upon request.</p> <p>5. During a tour on 10-27-15 at 1415 hours in the patient registration area, in the presence of staff A5, the quality coordinator, the staff A6 and A7, patient registration representatives, were requested to provide a copy of the State's Advance Directives brochure and no copy was located and made available from either registration staff at the time</p>		<p>Coordinator and Perioperative Charge Nurse are revising the policy and forms. This will be completed by 1/11/16. Registration and Pre-Op staff will be educated on these changes and changes will be implemented by 1/18/16. Adherence to policy will be monitored by Business Office Manager for Registration compliance and Perioperative Charge Nurse will monitor charts for correct completion of Pre-Operative record by clinical staff.</p>	

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Q 0225 Bldg. 00	<p>of the request.</p> <p>6. During an interview on 10-27-15 at 1415 hours, the staff A6 and A7, patient registration representatives, confirmed that a copy of the State Advanced Directives was not available in the registration area to provide to patients upon request. Staff A6 and A7 confirmed they were not aware of a requirement to provide a copy of the State Advanced Directives if requested when providing notice of center policy on Advance Directives.</p> <p>7. During an interview on 10-27-15 at 1445 hours, staff A1, the administrator, and staff A5, the quality coordinator confirmed that the center failed to ensure a copy of the State Advanced Directives was available and would be provided to patients if requested.</p> <p>416.50(d)(4),(5), & (6) SUBMISSION AND INVESTIGATION OF GRIEVANCES The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:</p> <p>(1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p>			

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	<p>(2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>(3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.</p> <p>Based on document review and interview, the grievance policy/procedure failed to indicate criteria to determine when a complaint must be regarded as a grievance and failed to ensure written notice of the decision was provided to a patient or patient's representative including the name of the center contact person, steps taken to investigate, and the date the process was completed for 2 of 14 complaints and grievances reviewed (patient #s 8, 24)</p> <p>Findings:</p> <p>1. Review of the policy/procedure Patient Grievances (approved 2-15) failed to indicate the following:</p> <p>A. criteria to determine when a complaint must be regarded as a grievance.</p> <p>B. a requirement for the written notice of</p>	Q 0225	We are revising our current Patient Grievances AD 1.059.03 policy to establish a grievance procedure for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance to our facility. This revised policy retitled Patient Grievances and Complaints will clearly define the difference between a patient complaint and a grievance and will delineate the proper steps to follow after it has been determined if it is in fact a complaint or a grievance. After these steps have been followed, written confirmation will be sent to the patient regarding the results. QI Coordinator is revising current policy to be reviewed and approved by the Executive Director. It will then be taken to the next scheduled Medical Quality Improvement (QI) Committee meeting for review and approval of committee. It will	02/01/2016

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	<p>determination to include the name of a contact person at the center, the steps taken to investigate the grievance, and the date the grievance process was completed.</p> <p>2. During an interview on 10-27-15 at 1450 hours, staff A1, the administrator, and staff A5, the quality coordinator confirmed the above.</p> <p>3. Review of grievance documentation dated 1-15-15 failed to indicate a written notice of the center determination was sent to patient #8.</p> <p>4. During an interview on 10-27-15 at 1430 hours, staff A1, the administrator, and staff A5, the quality coordinator confirmed that no written notice of determination was mailed to patient #8.</p> <p>5. Review of grievance documentation dated 9-29-14 failed to indicate a written notice of the center determination was sent to patient #24.</p> <p>6. During an interview on 10-27-15 at 1430 hours, staff A5, the quality coordinator confirmed that no written notice of determination was mailed to patient #24.</p>		<p>then be forwarded to Board of Managers for final approval. Upon final approvals, staff will be educated on proper procedure to follow for any complaint or grievance. Revision of policy will be completed by 12/31/15. Approval of policy by QI Committee and Board of Managers will be completed by 1/26/16. Education of staff and implementation of revised policy will be completed by 2/1/16.</p>	

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Q 0241 Bldg. 00	<p>416.51(a) SANITARY ENVIRONMENT</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>Based on document review, observation, and interview, the facility failed to ensure cleanliness and sanitation between cases, and at the end of the day, with terminal cleaning in 7 instances.</p> <p>Findings Include:</p> <p>1. Review of the policy Housekeeping/Sanitation, no policy number, last approved 2/3/15, indicated the cleanliness of the Center is maintained through consistent cleaning according to established routines, and that:</p> <p>A. During the surgical procedure, activities shall be directed to confine and contain contamination and areas outside the sterile field contaminated by organic debris should be cleaned as contamination occurs.</p> <p>B. Equipment and furniture shall be cleaned with an approved disinfectant cleaner after patient use.</p> <p>C. Patient transport carts shall be cleaned monthly with an approved disinfectant cleaner after each patient use.</p> <p>D. Floors shall be cleaned using an approved disinfectant cleaner. A clean</p>	O 0241	<p>APSC has a policy titled "Housekeeping/Sanitation", CL9.060.04, to insure that a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice is met. Policy was not being monitored closely enough resulting in non-compliance with policy. In addition, current policy will be revised to include "the patient transport carts shall be deep cleaned monthly with approved disinfectant cleaner". Also, <u>entire</u> cart will be cleaned and disinfected after each patient use. All staff will be reeducated on housekeeping procedures by 1/11/16 to insure ongoing compliance and enforcement of current policies. Revised policy will be completed by 12/30/15 by Clinical Director. Staff reeducation will be completed by 1/11/16. Clinical Director is developing a detailed check list for contracted cleaning staff to follow to prevent recurrence of all non-compliant cleaning issues. Check list will include an OR cleaning guide as well as a cleaning guide for all other clinical areas. Clinical Director will</p>	01/11/2016

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	<p>mop head and fresh disinfectant solution shall be used for each operating room procedure.</p> <p>2. At 4:40 PM on 10/26/15, interview with staff member #56, a contracted housekeeper, confirmed that this staff member utilizes one "flat head", microfiber, mop head for 7 of the OR (operating room) suites each night, and that they re-dip (double dip) the mop head in the disinfectant solution.</p> <p>3. At 12:35 PM on 10/28/15, interview with staff member #52, the clinical manager, confirmed that housekeeping staff are to use one mop head per OR suite, not one for all rooms, and that double dipping was not to occur.</p> <p>4. At 10:00 AM on 10/27/15, it was observed in pre op bay #6, in the company of staff member #52, the clinical director, that there was dust present on top of the vital signs monitor.</p> <p>5. At 10:05 AM on 10/27/15, it was observed in pre op room #15, in the company of staff member #53, the infection preventionist, that there was dust present on top of the suction monitor/regulator and canister.</p> <p>6. At 10:10 AM on 10/27/15, interview</p>		<p>implement cleaning checklist with contracted services and verify adherence by monthly observations to prevent deficiency from recurring. Cleaning checklist and observation sheets to be completed by 1/11/16 by Clinical Director. Warming Cabinets policy CL 9.229.01 will be revised to add "cabinet & door gaskets will be inspected for debris & cleaned if necessary on a monthly basis". This will be added to the monthly Quality Monitor forms which are completed by each area on a monthly basis. Revised policy and implementation of procedure will be completed by Clinical Director by 12/30/15. Clinical Director will be responsible for implementation and education on correcting this citation and monitoring monthly to ensure the deficiency does not reoccur. Completion Date will be 1/11/16.</p>				

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	<p>with staff members #52 and #53 confirmed that dust was present on vital signs monitors, the suction regulator, and suction canisters and that housekeeping staff needed to be more thorough in cleaning all surfaces.</p> <p>7. At 10:38 AM on 10/27/15, while on tour of the PACU (post anesthesia care unit), in the company of staff member #53, the infection preventionist, it was observed that two of the gurneys had an accumulation of dust on the base of the gurneys.</p> <p>8. At 10:40 AM on 10/27/15, interview with staff member #53 confirmed that the gurneys were dusty and that cleaning occurs on a monthly basis, not daily, or after each patient use, and per the monthly cleaning log, the gurneys were last cleaned on 10/1/15.</p> <p>9. At 10:45 AM on 10/27/15, while on tour of the Phase II recovery area in the company of staff member #53, the infection preventionist, it was observed that there was an accumulation of dust on the top of the code cart.</p> <p>10. At 10:45 AM on 10/27/15, staff member #53 confirmed that the top of the code cart was dusty.</p>			

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	<p>11. At 11:10 AM on 10/27/15, while in surgery suite #4, it was observed that there was a previous patient's blood (1/2 inch droplet and a > 4 inch streak of blood) on the C arm (radiologic equipment) to be used for pt. #4.</p> <p>12. Staff member #65, a surgery RN (registered nurse), was notified of the blood on the C arm and disinfected the area just prior to its use on pt. #4.</p> <p>13. Review of the policy for Warming Cabinets, no policy number, last approved on 2/3/15, indicated there was nothing in the policy related to cleaning of the warming cabinets.</p> <p>14. At 10:30 AM on 10/27/15, while on tour of the PACU area in the company of staff member #53, the infection preventionist, it was observed that there was an accumulation of dust under the lower shelf of the upper warming chamber of the blanket warmer.</p> <p>15. At 10:30 AM on 10/27/15, interview with staff member #53 confirmed the accumulation of dust in the warming cabinet, and that the cleaning of the blanket warmers is not on a routine schedule.</p>			

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Q 0242 Bldg. 00	<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 document review, observation, and interview, the infection control committee failed to follow its policies related to communicable disease history for 2 of 7 patient care staff, staff members N5 and N7; and related to OR (operating room) attire for 3 staff observed, staff members #59, #60, and #64.</p> <p>Findings Include: 1. Review of the policy Varicella (Chicken Pox) Immunization, no policy number, effective 3/6/12 and last approved 2/3/15, indicated all employees working at the Surgery Center are required to demonstrate immunity of varicella (chicken pox) by one of the following: a) written documentation by a physician of vaccination with two doses of varicella vaccine b) laboratory evidence of immunity or laboratory confirmation of disease c) diagnosis or</p>	O 0242	<p><u>Employee Health</u>: To insure compliance with all current policies related to communicable diseases, all employee charts will be reviewed by Employee Health Nurse for compliance. Employee Health Nurse will also be reeducated by the Infection Preventionist on all communicable diseases requirements and deadlines to be met for all new staff. To insure ongoing compliance with policy, all employee health records for new staff will be reviewed by both the Employee Health Nurse and a clinical supervisor(Peri-operative Charge Nurse or Clinical Director) before being filed. Completion to be done by 1/11/16. <u>Attire for Operating Room</u>: AORN standards were reviewed and we are revising our current policy titled, Attire for Operating Room CL 9.007.02 to reflect AORN standards. The following language :“personnel with facial hair should wear disposable hood” will be removed from the</p>	01/12/2016

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	<p>verification of a history of varicella disease by a physician.</p> <p>2. Review of the policy Rubeola and Rubella Immunization, no policy number, effective 7/18/07 and last approved on 2/3/15, indicated new employees hired on or after the effective date of this policy will demonstrate immunity by one of the following: a. have a Rubella titre drawn as proof of immunity b. present documentation of physician-diagnosed German measles (Rubella) c. present written documentation that two doses of Rubella and Rubeola (MMR) vaccine were received on or after the first birthday.</p> <p>3. Review of personnel files indicated staff member N5, an orderly, was hired 4/14/14 and lacked information related to Rubella and Rubeola, and staff member N7, a surgery nurse, was hired 11/4/14, and had a self reported history of disease for Varicella.</p> <p>4. At 9:50 AM on 10/28/15, interview with staff member #52, the clinical director, confirmed that facility policies were not followed for staff members N5 and N7, as stated above, and no further documentation was provided prior to exit.</p>		<p>policy to reflect current practice. Clinical Director will hold staff meeting by 1/11/16 to advise staff of revision to policy and also to reeducate on APSC proper attire policy and strict compliance. Completion to be done by 1/11/16. *** 1/12/16 - CORRECTION UPDATE *** OR Charge Nurse will conduct daily checks on all personnel in the semi-restricted and restricted areas of the operating room. Any non-compliance offenders will be immediately addressed. Clinical Director, Quality Assurance Coordinator and the Infection Preventionist will continuously monitor for non-compliance and address non-compliance offenders immediately. Completion date of 1/12/16</p>				

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	<p>5. Review of the policy Attire for Operating Room, no policy number, effective date 5/5/08 and last approved on 2/3/15, indicated that proper attire in the semi-restricted areas shall include approved Center-supplied bouffant cap/hat or hood, earrings must be contained within the scrub cap at all times, and personnel with facial hair should wear - disposable hood.</p> <p>6. At 10:55 AM on 10/27/15, while observing surgery in OR #4, it was observed that staff member #59, a circulating RN (registered nurse), had earrings that were not covered by the surgical cap.</p> <p>7. At 11:10 AM on 10/27/15, while observing surgery in OR #4, it was observed that:</p> <p>A. The rad tech, staff member #60, had hair that was not covered by the skull cap worn, and had side burns that were not covered.</p> <p>B. The resident, staff member #64, had hair not covered by the skull cap worn.</p> <p>4. At 9:50 AM on 10/28/15, interview with staff member #52, the clinical director, confirmed that staff, as stated above, were not in compliance with the facility surgical attire policy. No further documentation was provided prior to</p>			

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S 0000 Bldg. 00	exit. The visit was for a licensure survey. Facility Number: 010984 Survey Date: 10-26/28-15 QA: cjl 12/02/15	S 0000		
S 0172 Bldg. 00	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L) Require that the chief executive officer develop and implement policies and programs for the following: (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. Based on document review and interview, the governing board failed to ensure the implementation of its policy	S 0172	To insure compliance with all current policy related to TB (tuberculin) testing, all employee charts will be reviewed by	01/11/2016

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	<p>regarding TB (tuberculin) testing for one employee hired in 2015, staff member N6.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> 1. Review of the policy Tuberculosis Screening for Employees, no policy number, effective 3/11/11 and last approved on 2/3/15, indicated all employees working at the Surgery Center are required to have a mandatory two step TB screening for tuberculosis infection and disease and that written documented evidence of TB screening performed elsewhere will also be acceptable. 2. Review of personnel files indicated staff member N6, a certified surgical tech, was hired 8/17/15 and had only one TB test done upon hire. The previous, outside agency, TB test was noted as being done in 2013. 3. At 9:15 AM on 10/28/15, interview with staff member #53, the infection preventionist, confirmed that the previous TB test documented for staff member N6 was in 2013, and that CDC (centers for disease control and prevention) requires the previous TB test, from a former agency or employer, to have been within 12 months of the time of hire, that staff member N6 was beyond the 12 months at the time of hire, and that staff member 		<p>Employee Health Nurse for compliance. Employee Health Nurse will also be reeducated by the Infection Preventionist on all communicable diseases requirements and deadlines to be met for all new staff. To insure ongoing compliance with policy, all employee health records for new staff will be reviewed by both the Employee Health Nurse and a clinical supervisor (Peri-operative Charge Nurse or Clinical Director) before being filed. Completion to be done by 1/11/16.</p>	

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S 0226 Bldg. 00	<p>N6 should have had a two step TB test done in August of 2015. No further documentation was provided prior to exit.</p> <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 and interview, the center failed to maintain its list of all contracted services, including the scope and nature of services provided, for 6 contracted services (three (3) fire protection providers, a specialty pharmaceutical provider, an operating room air quality certification service, and a radiation exposure monitoring provider).</p> <p>Findings:</p> <p>1. Review of a list of contracted services dated 1-31-14 indicated an agreement with CS1, a pharmacy compounding</p>	S 0226	<p>Business Office Manager will bring current a list detailing contracted services and will also add to the list the "scope and nature of services provided". After completion, she will monitor bi-weekly so any additions, deletions or revisions to contracts are kept current and prevent the deficiency from reoccurring. Completion date will be 1/11/16.</p>	01/11/2016

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S 0320 Bldg. 00	<p>service, and CS2, a fire alarm system testing and certification service that was no longer providing services at the center and failed to indicate the name of a radiation badge monitoring service.</p> <p>2. Review of center documentation indicated the following: CS3, a fire alarm testing and certification service provider under agreement until 3-15, CS4, a fire extinguisher service, CS5, a fire sprinkler service, CS6, an operating room air quality service, CS7, a radiation exposure monitoring provider under agreement until 12-14, and CS7, a radiation exposure monitoring company currently providing services for the center.</p> <p>3. During an interview on 10-27-15 at 1500 hours, staff A1, the administrator, and staff A5, the quality coordinator confirmed that the list of contracted services had not been maintained.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(2)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(2) All functions, including, but not limited to, the following:</p>			

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	<p>(A) Discharge and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the center failed to ensure its patient transfers were evaluated and reviewed through its medical quality improvement committee (MQIC) for 1 transfer identified in 2015 program documentation.</p> <p>Findings include:</p> <ol style="list-style-type: none"> The policy/procedure Medical Quality Improvement (QI) Risk Management Program (approved 2-15) indicated an Adverse Event Report would be completed for all risk management issues and indicated the MQIC committee would evaluate all patient transfers. The 1st quarter 2015 MQIC minutes dated 4-21-15 indicated the following: The QI report was presented for the physician review. The report was not read in its entirety and only areas requiring discussion were covered. The MQIC minutes failed to indicate a committee discussion, recommendation, or action regarding the one hospital transfer identified in the attached Quality Improvement Report during the committee meeting. 	S 0320	<p>A separate line item will be added to the Medical Quality Improvement(QI) Meeting Minutes listing "Transfers and ER Visits". All information pertaining to any transfers or ER visits will be contained in the QI meeting packet to be reviewed by the QI Committee during the meeting. To insure ongoing compliance, the QI Coordinator will be provided information on all Transfers and ER visits at the time they occur so they can be tracked and added to the QI Meeting Agenda under the topic "Risk Management". The QI Coordinator will be responsible for preparing the QI Committee Meeting packet and presenting to the Executive Director for review and approval prior to each quarterly QI meeting. This process will be implemented with the next scheduled Medical Quality Improvement (QI) Committee meeting to be held on January 19, 2016.</p>	01/19/2016	

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S 0442 Bldg. 00	<p>3. During an interview on 10-28-15 at 1100 hours, staff A5, the quality coordinator, confirmed that the April, 2015 MQIC minutes failed to indicate documentation of committee member discussion or recommendations associated with a review of the patient transfer reported in the QI report and no other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</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>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on document review and interview, the infection control committee failed to follow its policies related to communicable disease history for 2 of 7 patient care staff, staff</p>	S 0442	To insure compliance with all current policies related to communicable diseases, all employee charts will be reviewed by Employee Health Nurse for compliance. Employee Health Nurse will also be reeducated by	01/11/2016

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	<p>members N5 and N7, and failed to ensure the implementation of its policy regarding TB (tuberculin) testing for one employee hired in 2015, staff member N6.</p> <p>Findings Include:</p> <p>1. Review of the policy Varicella (Chicken Pox) Immunization, no policy number, effective 3/6/12 and last approved 2/3/15, indicated all employees working at the Surgery Center are required to demonstrate immunity of varicella (chicken pox) by one of the following: a) written documentation by a physician of vaccination with two doses of varicella vaccine b) laboratory evidence of immunity or laboratory confirmation of disease c) diagnosis or verification of a history of varicella disease by a physician.</p> <p>2. Review of the policy Rubeola and Rubella Immunization, no policy number, effective 7/18/07 and last approved on 2/3/15, indicated new employees hired on or after the effective date of this policy will demonstrate immunity by one of the following: a. have a Rubella titre drawn as proof of immunity b. present documentation of physician-diagnosed German measles (Rubella) c. present written documentation that two doses of Rubella and Rubeola (MMR) vaccine</p>		<p>the Infection Preventionist on all communicable diseases requirements and deadlines to be met for all new staff. To insure ongoing compliance with policy, all employee health records for new staff will be reviewed by both the Employee Health Nurse and a clinical supervisor (Peri-operative Charge Nurse or Clinical Director) before being filed. Completion to be done by 1/11/16.</p>		

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	<p>were received on or after the first birthday.</p> <p>3. Review of personnel files indicated staff member N5, an orderly, was hired 4/14/14 and lacked information related to Rubella and Rubeola, and staff member N7, a surgery nurse, was hired 11/4/14, and had a self reported history of disease for Varicella.</p> <p>4. At 9:50 AM on 10/28/15, interview with staff member #52, the clinical director, confirmed that facility policies were not followed for staff members N5 and N7, as stated above, and no further documentation was provided prior to exit.</p> <p>5. Review of the policy Tuberculosis Screening for Employees, no policy number, effective 3/11/11 and last approved on 2/3/15, indicated all employees working at the Surgery Center are required to have a mandatory two step TB screening for tuberculosis infection and disease and that written documented evidence of TB screening performed elsewhere will also be acceptable.</p> <p>6. Review of personnel files indicated staff member N6, a certified surgical tech, was hired 8/17/15 and had only one TB test done upon hire. The previous,</p>			

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S 0444 Bldg. 00	<p>outside agency, TB test was noted as being done in 2013.</p> <p>7. At 9:15 AM on 10/28/15, interview with staff member #53, the infection preventionist, confirmed that the previous TB test documented for staff member N6 was in 2013, and that CDC (centers for disease control and prevention) requires the previous TB test, from a former agency or employer, to have been within 12 months of the time of hire, that staff member N6 was beyond the 12 months at the time of hire, and that staff member N6 should have had a two step TB test done in August of 2015. No further documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(ix)</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>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p>			

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	<p>Based on document review, observation, and interview, the infection control preventionist failed to implement the facility policy regarding OR (operating room) attire for 3 staff observed, staff members #59, #60, and #64.</p> <p>Findings Include:</p> <p>1. Review of the policy Attire for Operating Room, no policy number, effective date 5/5/08 and last approved on 2/3/15, indicated that proper attire in the semi-restricted areas shall include approved Center-supplied bouffant cap/hat or hood, earrings must be contained within the scrub cap at all times, and personnel with facial hair should wear - disposable hood.</p> <p>2. At 10:55 AM on 10/27/15, while observing surgery in OR #4, it was observed that staff member #59, a circulating RN (registered nurse), had earrings that were not covered by the surgical cap.</p> <p>3. At 11:10 AM on 10/27/15, while observing surgery in OR #4, it was observed that:</p> <p>A. The radiology tech, staff member #60, had hair that was not covered by the skull cap worn, and had side burns that were not covered.</p> <p>B. The resident, staff member #64, had</p>	S 0444	<p>AORN standards were reviewed and we are revising our current policy titled, Attire for Operating Room CL 9.007.02 to reflect AORN standards. The following language: "personnel with facial hair should wear disposable hood" will be removed from the policy to reflect current practice. Clinical Director will hold staff meeting by 1/11/16 to advise staff of revision to policy and also to reeducate on APSC proper attire policy and strict compliance. Completion to be done by 1/11/16.</p> <p>*** 1/12/16 - CORRECTION UPDATE ***</p> <p>OR Charge Nurse will conduct daily checks on all personnel in the semi-restricted and restricted areas of the operating room. Any non-compliance offenders will be immediately addressed. Clinical Director, Quality Assurance Coordinator and the Infection Preventionist will continuously monitor for non-compliance and address non-compliance offenders immediately. Completion date of 1/12/16</p>	01/12/2016			

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S 0526 Bldg. 00	<p>hair not covered by the skull cap worn.</p> <p>4. At 9:50 AM on 10/28/15, interview with staff member #52, the clinical director, confirmed that staff, as stated above, were not in compliance with the facility surgical attire policy. No further documentation was provided prior to exit.</p> <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 document review and interview, the facility failed to ensure that nursing staff who perform laboratory testing had annual competencies documented for 1 of 1 RN (registered nurse) who might be performing these tests, RN N3.</p> <p>Findings Include: 1. Review of employee files indicated that RN N3 lacked documentation of competency for laboratory testing done for patients at the facility.</p> <p>2. At 11:50 AM on 10/28/15, interview</p>	S 0526	All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment. Competencies for glucose, urine HCG, PT/INR, and Hemocue will be created for all staff that will be performing these tests. These new competencies will be given annually and will be included in RN orientation. Due to the holidays and staff scheduling, this will not be completed until 2/8/15. This will be implemented by the Perioperative Charge Nurse.	02/08/2016

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S 0772 Bldg. 00	<p>with staff member #52, the clinical director, confirmed that there was currently no annual competencies checked, or documented, for nursing personnel related to laboratory point of care testing performed by staff at the facility. No further documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the</p>			

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	<p>report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based on document review and interview, the medical staff failed to follow its rules and regulations related to history and physicals (H & Ps) for 1 of 1 patient for physician #61, patient #4.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> Review of the medical staff rules and regulations approved on 8/18/15, indicated on page 4 under section 8., Medical Records: c. upon admission, each patient must have a comprehensive medical evaluation completed by a privileged member of the medical staff. The original history and physical must be no more than 30 days before the date of the scheduled procedure to be eligible to be updated. Review of patient medical records indicated that patient #4 had an office H & P dated 9/11/15 with surgery on 10/27/15. At 11:50 AM on 10/28/15, interview with staff member #52, the clinical director, confirmed that the H & P for patient #4 was greater than 30 days, and that the brief H & P, on the form titled Indications for Surgery/Surgeon's Admitting Notes, was not complete 	S 0772	<p>Medical staff will be required to review rules and regulations associated with the standard concerning updated H & P's. A letter from the Medical Director will be sent to all physicians along with the rules and regulations pertaining to this topic by 1/8/16. Pre-operative staff will be re-educated on the requirements of the H & P by the Medical Director by 1/11/16. For all cases they will verify H & P date is within 30 days of the procedure. If outdated by the 30 day criteria, a comprehensive H & P will be presented for completion by the Surgeon prior to patient surgical procedure or case will be cancelled. This topic will be presented at the next scheduled Medical Quality Improvement (QI) committee meeting on 1/19/16 for discussion and any further input.</p>	01/19/2016

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S 0888 Bldg. 00	<p>enough to consider it the brief H & P that can be completed on the day of surgery. No other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(F)</p> <p>Requirement for surgical services include:</p> <p>(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:</p> <p>(F) A requirement for an operative report describing techniques, findings, and tissue removed or altered to be written or dictated immediately following surgery and authenticated by the surgeon in accordance with center policy and governing body approval.</p> <p>Based on document review and interview, the medical staff failed to follow its rules and regulations related to operative notes for 1 of 1 patients for physician #64, patient #3.</p> <p>Findings Include: 1. Review of the medical staff rules and regulations approved on 8/18/15, indicated on page 4 under section 8., a</p>	S 0888	Medical staff will be required to review rules and regulations associated with the standard concerning Operative Report written or dictated immediately after procedure. A letter from the Medical Director will be sent to all physicians along with the rules and regulations pertaining to this topic by 1/8/16. Medical Records will verify dictation postoperatively was completed by either written	01/19/2016

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S 0920 Bldg. 00	<p>standard operative note by the operating physician...is to be written or dictated immediately after the procedure.</p> <p>2. Review of medical records indicated patient #3 had surgery on 6/24/15 and had an area checked at the bottom of form APSC-127 (Allied Physicians Surgery Center) indicating that an operative report was dictated immediately post op. The rest of the area was blank and the dictated report was dated 6/25/15.</p> <p>3. At 11:50 AM on 10/28/15, interview with staff member #52, the clinical director, indicated that if the brief post op area on the bottom of form APSC-127 is completed, the physicians can dictate their op reports after the day of surgery. Physician #64 did not complete the bottom of the form and checked that they had dictated their report immediately following surgery, but the dictated report indicates this occurred on 6/25/15, thus not per medical staff rules and regulations. No other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(b)</p> <p>(b) Written patient care policies and</p>		<p>post-operative note or dictation for compliance with policy. Any non-compliance will be reported to the Medical Director for immediate follow-up with non-compliant physician. If not completed within 24 hours, physician will be suspended until complete. This topic will be presented at the next QI committee on 1/19/16 and process will be discussed and evaluated. No changes in rules and regulations at this time will be made. Plan of action is enforcement of current rules and regulations.</p>		

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	<p>procedures shall be available to personnel and shall include, but not be limited to, the following: Based on document review and interview, the facility failed to ensure that patient care policies related to medication administration were followed for 1 of 1 patient with post anesthesia orders written by physician #66, patient #8.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> 1. Review of the policy Medication Guidelines - Administration and Storage, no policy number, last approved 2/3/15, indicated that medication administration will include the following checks immediately before giving the drug: the right medication, in the right dose, to the right person, by the right route, at the right time. 2. Review of medical records indicated that orders written by anesthesiologist #66 for pt. #8 on 10/3/14 were for Fentanyl 50 mcg (micrograms) every 2 to 5 minutes as needed for pain with a maximum of 200 mcg., and that nursing noted giving 25 mcg at 1:22 PM, and again at 1:27 PM, on 10/3/14. 3. At 2:45 PM on 10/27/15, interview with staff member #50, the executive director, confirmed that pt. #8 received 25 mcg of Fentanyl two times, when the 	S 0920	<p>Medication Guidelines - Administration and Storage CL 9.073.12 policy and procedure will be revised as follows: "All persons who administer medications may divert pain/nausea medication and the patient may receive a replacement of lesser or not strength", (per language taken from AORN standard RP-Medication Safety,X.a.2). Revised policy will reflect current medication practices. Clinical Director will be responsible for implementation and education of all staff. Annual review of all policies and procedures will be completed by the Governing Body. Completion date of 1/11/16.</p> <p>*** 1/12/16 - CORRECTION UPDATE ***</p> <p>APSC has a policy titled, "Medication Guidelines –Administration and Storage" CL 9.073.12 to ensure the 5 rights of medicationadministration are followed. The policyintended guidelines were not properly carried out by staff members in regardsto proper dosing of medications to patients.</p> <p>Reeducation to all perioperative RN's by the ClinicalDirector and Perioperative Charge Nurse will begin immediately and completed by1/18/16. A letter from the</p>	01/25/2016

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S 1146 Bldg. 00	<p>order was for 50 mcg., thus not per physician orders.</p> <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 document review, observation, and interview, the facility failed to ensure that no condition was created that might cause a hazard to patients in relation to glucometer control solutions and test strips in one of three areas with these supplies, the pre op nursing area; and that might cause a hazard to employees in regard to the lack of MSDS (materials safety data sheets) in two of two</p>	S 1146	<p>MedicalDirector will be sent to all credentialed anesthesiologist by 1/15/16 to reinforce the necessity of dose specific medication orders. Random chart audits will be completed from 2/1/16 thru 2/29/16 to ensure proper compliance. Further reviews will be completed during the 2nd quarter nursing chart audit. Completion date of 1/25/16</p> <p>Control Test policy CL 9.207.04 was not being followed. Staff will be reeducated on current Glucometer control solutions policy. Glucometer control solutions will be added to monthly outdate list to be completed by staff. Perioperative Charge Nurse will educate staff and implement by 1/11/16. MSDS binders are labeled in Red and kept in Materials Manager's</p>	01/11/2016

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	<p>housekeeping closets.</p> <p>Findings Include:</p> <ol style="list-style-type: none"> Review of the policy regarding Control Tests, no policy number, last approved on 2/3/15, indicated that when a new bottle of control solution is opened for blood glucose controls, the expiration date will be written on the label. The control solution is good for three months from that date or until the expiration date on the bottle, whichever comes first. Also, when a new bottle of blood glucose control strips is opened, the control strips are good for 120 days from that date or until the expiration date on the bottle, whichever comes first. At 10:10 AM on 10/27/15, while on tour of the pre op area in the company of staff member #52, the clinical director, it was observed that the glucometer control solutions (two vials) had an expiration date of 9/25/15 and that the test strip vial had no documentation of an opened date or a 120 day expiration date At 10:10 AM on 10/27/15, staff member #52 confirmed that the control solutions and test strips were not dated, or replaced, per facility policy, and no further documentation was provided prior to exit. 		<p>office. Duplicate binders were created on 10/27/15 and placed in housekeeping closets on 10/28/15. To insure that binders are up to date, Materials Manager will be responsible to obtain any new MSDS sheets when new cleaning products are purchased and place them in MSDS binders.</p>	

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S 1174 Bldg. 00	<p>4. At 4:30 PM on 10/26/15, while on tour of the non-restricted areas of the facility in the company of staff member #55, the housekeeping supervisor, it was observed in the housekeeping closet that there was no MSDS information, or binder, that would instruct housekeeping staff how to care for any splash/contact event from the products used in cleaning the facility.</p> <p>5. At 11:45 AM on 10/27/15, while on tour of the semi restricted area of the facility in the company of staff member #52, the clinical director, it was observed in the housekeeping closet that there was no MSDS information, or binder, that would instruct housekeeping staff how to care for any splash/contact event from the products used in cleaning the facility.</p> <p>6. At 9:50 AM on 10/28/15, interview with staff member #52 confirmed that the facility had only one MSDS binder and it was located in the materials coordinator's office and not readily available to housekeeping staff if it would be needed in an emergency. No other documentation was provided prior to exit,</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE,</p>			

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	<p>410 IAC 15-2.5-7(b)(5)(A)</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>(5) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:</p> <p>(A) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:</p> <p>(i) Asepsis. (ii) Cross-contamination prevention. (iii) Safe practice.</p> <p>Based on document review, observation, and interview, the facility failed to ensure cleanliness and sanitation between cases, and at the end of the day, with terminal cleaning in 7 instances.</p> <p>Findings Include: 1. Review of the policy Housekeeping/Sanitation, no policy number, last approved 2/3/15, indicated the cleanliness of the Center is maintained through consistent cleaning according to established routines, and</p>	S 1174	<p>APSC has a policy titled "Housekeeping/Sanitation", CL9.060.04, to insure that a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice is met. Policy was not being monitored closely enough resulting in non-compliance with policy. In addition, current policy will be revised to include "the patient transport carts shall be deep cleaned monthly with approved disinfectant cleaner". Also, <u>entire</u></p>	01/11/2016

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	<p>that:</p> <p>A. During the surgical procedure, activities shall be directed to confine and contain contamination and areas outside the sterile field contaminated by organic debris should be cleaned as contamination occurs.</p> <p>B. Equipment and furniture shall be cleaned with an approved disinfectant cleaner after patient use.</p> <p>C. Patient transport carts shall be cleaned monthly with an approved disinfectant cleaner after each patient use.</p> <p>D. Floors shall be cleaned using an approved disinfectant cleaner. A clean mop head and fresh disinfectant solution shall be used for each operating room procedure.</p> <p>2. At 4:40 PM on 10/26/15, interview with staff member #56, a contracted housekeeper, confirmed that this staff member utilizes one "flat head", microfiber, mop head for 7 of the OR (operating room) suites each night, and that they re-dip (double dip) the mop head in the disinfectant solution.</p> <p>3. At 12:35 PM on 10/28/15, interview with staff member #52, the clinical manager, confirmed that housekeeping staff are to use one mop head per OR suite, not one for all rooms, and that double dipping was not to occur.</p>		<p>cart will be cleaned and disinfected after each patient use. All staff will be reeducated on housekeeping procedures by 1/11/16 to insure ongoing compliance and enforcement of current policies. Revised policy will be completed by 12/30/15 by Clinical Director. Staff reeducation will be completed by 1/11/16. Clinical Director is developing a detailed check list for contracted cleaning staff to follow to prevent recurrence of all non-compliant cleaning issues. Check list will include an OR cleaning guide as well as a cleaning guide for all other clinical areas. Clinical Director will implement cleaning checklist with contracted services and verify adherence by monthly observations to prevent deficiency from recurring. Cleaning checklist and observation sheets to be completed by 1/11/16 by Clinical Director. Warming Cabinets policy CL 9.229.01 will be revised to add "cabinet & door gaskets will be inspected for debris & cleaned if necessary on a monthly basis". This will be added to the monthly Quality Monitor forms which are completed by each area on a monthly basis. Revised policy and implementation of procedure will be completed by Clinical Director by 12/30/15. Clinical Director will be responsible for implementation and education on</p>				

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	<p>4. At 10:00 AM on 10/27/15, it was observed in pre op bay #6, in the company of staff member #52, the clinical director, that there was dust present on top of the vital signs monitor.</p> <p>5. At 10:05 AM on 10/27/15, it was observed in pre op room #15, in the company of staff member #53, the infection preventionist, that there was dust present on top of the suction monitor/regulator and canister.</p> <p>6. At 10:10 AM on 10/27/15, interview with staff members #52 and #53 confirmed that dust was present on vital signs monitors, the suction regulator, and suction canisters and that housekeeping staff needed to be more thorough in cleaning all surfaces.</p> <p>7. At 10:38 AM on 10/27/15, while on tour of the PACU (post anesthesia care unit), in the company of staff member #53, the infection preventionist, it was observed that two of the gurneys had an accumulation of dust on the base of the gurneys.</p> <p>8. At 10:40 AM on 10/27/15, interview with staff member #53 confirmed that the gurneys were dusty and that cleaning occurs on a monthly basis, not daily, or</p>		<p>correcting this citation and monitoring monthly to ensure the deficiency does not reoccur. Completion Date will be 1/11/16.</p>	

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	<p>after each patient use, and per the monthly cleaning log, the gurneys were last cleaned on 10/1/15.</p> <p>9. At 10:45 AM on 10/27/15, while on tour of the Phase II recovery area in the company of staff member #53, the infection preventionist, it was observed that there was an accumulation of dust on the top of the code cart.</p> <p>10. At 10:45 AM on 10/27/15, staff member #53 confirmed that the top of the code cart was dusty.</p> <p>11. At 11:10 AM on 10/27/15, while in surgery suite #4, it was observed that there was a previous patient's blood (1/2 inch droplet and a > 4 inch streak of blood) on the C arm (radiologic equipment) to be used for pt. #4.</p> <p>12. Staff member #65, a surgery RN (registered nurse), was notified of the blood on the C arm and disinfected the area just prior to its use on pt. #4.</p> <p>13. Review of the policy for Warming Cabinets, no policy number, last approved on 2/3/15, indicated there was nothing in the policy related to cleaning of the warming cabinets.</p> <p>14. At 10:30 AM on 10/27/15, while on</p>			

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NAME OF PROVIDER OR SUPPLIER ALLIED PHYSICIANS SURGERY CENTER LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 53990 CARMICHAEL DR STE 100 SOUTH BEND, IN 46635
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S 1180 Bldg. 00	<p>tour of the PACU area in the company of staff member #53, the infection preventionist, it was observed that there was an accumulation of dust under the lower shelf of the upper warming chamber of the blanket warmer.</p> <p>15. At 10:30 AM on 10/27/15, interview with staff member #53 confirmed the accumulation of dust in the warming cabinet, and that the cleaning of the blanket warmers is not on a routine schedule.</p> <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 failed to maintain its safety program and plan including a written description of the committee membership, meeting requirements, and safety functions to be reviewed by the committee.</p>	S 1180	The format of the current QI Committee Meeting will be changed to allow for a separate meeting for the Safety Committee. All information pertaining to any safety related issues will be contained in a separate folder as part of the QI meeting packet to be distributed	01/19/2016

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	<p>Findings include:</p> <ol style="list-style-type: none"> 1. Review of the policy/procedure Safety Committee Program (approved 2-15) failed to indicate a description of the committee membership or committee meeting requirements. The policy/procedure failed to indicate how it would monitor facility, staff, patients and physicians thereby ensuring a safe environment and failed to indicate the quality improvement (QI) monitors it would evaluate that were considered safety issues. 2. The policy/procedure Medical Quality Improvement (QI) Risk Management Program (approved 2-15) indicated the following: Responsibilities of the Medical Quality Improvement Committee (MQIC) ... Any Safety Committee minutes are reviewed. The MQIC program description failed to indicate if the MQIC committee was performing the safety committee function during the MQIC meetings. 3. Review of the medical quality improvement committee (MQIC) meetings and quality improvement reports dated 7-21-14, 1-20-15, 4-21-15, and 7-21-15 indicated the following: No safety committee meeting was held 		<p>to all QI Committee members. The QI Coordinator will be responsible for preparing the Safety packet and presenting to the Executive Director for review and approval prior to each quarterly QI meeting. This process will be implemented with the next scheduled Medial Quality Improvement (QI) Committee meeting to be held on January 19, 2016. A revision to our current Safety Committee Program AD 5.007.01 policy to reflect this change will be completed by 12/30/15 by the QI Coordinator.</p>	

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S 1210 Bldg. 00	<p>during this quarter.</p> <p>4. During an interview on 10-28-15 at 1110 hours, staff A5, the quality coordinator, confirmed that no documentation of 2015 safety committee meetings was available and no other documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAC 15-2.5-8(c)(1)</p> <p>(c) All centers shall comply with all regulations set forth in this rule and with 410 IAC 5, when radiology services are provided on-site by the center, including, but not limited to the following:</p> <p>(1) Radiology services must be supervised by a radiologist or radiation oncologist.</p> <p>Based upon document review and interview, the center failed to ensure that its radiology services were supervised by a radiologist.</p> <p>Findings:</p> <p>1. On 10-26-15 at 1030 hours, staff A1, the administrator, was requested to provide documentation indicating that the center radiologic services were supervised by a credentialed radiologist</p>	S 1210	A Radiologist will be appointed by the Governing Body to review all Radiology policy and procedures, quarterly dosimetry reports, regular equipment inspections and hazard corrections, review of lead apron shielding inspection, review of facility state licensure and all radiologic technologist's licenses. A Letter of Agreement will be drafted and signed by Radiologist and the Governing Body and will be reviewed on an annual basis to insure that all requirements are being met. The	01/19/2016

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S 1222 Bldg. 00	<p>and none was provided prior to exit.</p> <p>2. Review of 2014 and 2015 radiation dosimetry reports, radiology equipment calibration reports, radiology safety policy/procedures, and lead apron shielding inspection reports failed to indicate that a review by a radiologist had been performed.</p> <p>3. During an interview on 10-28-15 at 1035 hours, staff A3, the clinical director confirmed that a qualified medical physicist was supervising the radiologic services provided at the center and confirmed that the radiologic services lacked documentation of supervision by a radiologist.</p> <p>410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAC 15-2.5-8(e)</p> <p>(e) Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:</p> <p>(1) Proper safety precautions must be maintained against radiation hazards in accordance with the center's radiation and safety program(s).</p> <p>(2) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and</p>		<p>QI Coordinator will provide all data to the Radiologist for review on an annual basis. The results of this review will be included in the first QI Committee meeting following this annual review. Letter of Agreement will be prepared and signatures obtained by January 19, 2016.</p>				

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	<p>state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.</p> <p>Based on document review and interview, the center failed to ensure that all female patients of childbearing age were screened to minimize the potential for exposing a fetus to ionizing radiation.</p> <p>Findings:</p> <ol style="list-style-type: none"> Review of the policy/procedure Radiology, Radiation Safety (approved 2-15) indicated the following: Measures to protect patients from direct and indirect radiation exposure should be documented on the peri-operative or intra-operative nursing record. The policy/procedure failed to indicate the specific measures to be taken and documented. Review of the policy/procedure Pre-Operative Evaluation of Patients, by Center's Pre-op Nurses (approved 2-15) indicated the following: Urine [human chorionic gonadotropin] HCG will be run as ordered or as a nursing judgment when there is a suspicion of pregnancy. (sic) Late menstrual cycle or there is no use of birth control. The policy/procedure failed to ensure that a urine pregnancy test was performed on all potentially pregnant female patients of childbearing age 	S 1222	<p>Pre-Operative Evaluation of Patients by the Center's Pre-Operative Nurses CL 9.096.04 and Radiology, Radiation Safety CL 9.098.04 policy and procedures will be revised to include "urine HCG will be obtained on all females who have started their menses through one year post menopause" (exceptions post hysterectomy and tubal ligation patients). Education of new testing requirement for patients will be conducted for all staff members. This will insure that all female patients of child bearing age were screened to minimize the potential for exposing a fetus to ionizing radiation. Clinical Director and Perioperative Charge Nurse will educate all staff members to policy revisions and new testing requirements. Completion date of 1/11/16.</p>	01/11/2016

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	<p>before any exposure to ionizing radiation would occur.</p> <p>3. During an interview on 10-26-15 at 1520 hours, staff A1, the administrator, confirmed that the policy/procedures failed to ensure a urine pregnancy test would be performed on all female patients with a potential for being pregnant before the start of any surgical procedure utilizing ionizing radiation.</p>				