

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001128	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 11/02/2011
NAME OF PROVIDER OR SUPPLIER MEDICAL CONSULTANTS ENDOSCOPY CENTER LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 800 S TILLOTSON AVE MUNCIE, IN 47304		
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Q0000	The visit was for a re-certification survey. Facility Number: 003754 Survey Date: 10-31-11 to 11-02-11 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor QA: 11/23/11	O0000			

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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Q0083	<p>416.43(d) PERFORMANCE IMPROVEMENT PROJECTS</p> <p>(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.</p> <p>(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results</p> <p>Based on document review and interview, the center failed to conduct and document an annual performance improvement project(s) including a rationale for the project and evaluation of effectiveness.</p> <p>Findings:</p> <p>1. On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation of a current performance improvement project for improving patient health outcomes or safety in the center as well as any project completed in the past year and none was provided prior to exit from the facility.</p> <p>2. The policy/procedure Quality Assessment Program (reviewed 09-25-11) failed to indicate that the center would conduct distinct, focused improvement projects annually with documentation of the projects being conducted.</p>	O0083	<p>Annual performance improvement project with rationale and evaluation of effectiveness. 1. Privacy concern- talking with responsible adults and /or driver as we bring into recovery room with patient concerning details of procedure and looking at limiting visitor per patient and no children under 12age. 2. Infection control -cleaning process of area between patient in procedure room and pre and post. 3. Supplies cost and clinical use comparison between disposables. 4. Clinical outcome and peer review of physician on time out, cecum recorded, total withdraw time, polyps and pathology. Review with staff possible rational project due to deficiency and approved by medical and governing board. Conduct implemented 12/02/11 projects starting 1/9/12. Monitoring by Infection Control Nurse, Safety Nurse and the Administrator. Empowering other personnel to</p>	12/02/2011			

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	3. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the facility failed to document an annual performance improvement project or action plan including the reason for implementing the project, expected outcomes, and an evaluation of the project's effectiveness.		enforce monitoring of the process.		

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Q0105	<p>416.44(c) EMERGENCY EQUIPMENT Emergency equipment available to the operating rooms must include at least the following:</p> <ul style="list-style-type: none"> (1) Emergency call system. (2) Oxygen. (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator. (4) Cardiac defibrillator. (5) Cardiac monitoring equipment. (6) Tracheostomy set. (7) Laryngoscopes and endotracheal tubes. (8) Suction equipment. (9) Emergency medical equipment and supplies specified by the medical staff. <p>Based on document review and interview, the facility failed to have required emergency equipment available for use for 2 of 9 items of required emergency equipment.</p> <p>Findings:</p> <p>1) The policy/procedure Crash Cart Inventory (reviewed 07-20-11) failed to indicate a tracheostomy set or cricoidotomy set and a ventilator was listed as available for use on the code cart.</p> <p>2) During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedure lacked the required equipment.</p>	00105	<p>The policy and procedure failed to indicate a tracheostomy set or ventilator listed available even though present on the Crash Cart. The policy and procedure for the Crash Cart inventory was changed as follows: 1. Name changed to Emergency Cart on all policies and checklists for consistency throughout the facility. 2 The Quicktrach and Voltran Automatic Resuscitator which is available in the facility was added to Emergency Cart policy and checklist. 3 These changes to the Emergency cart policy and checklists were reviewed with staff during a staff meeting 11/17/11. Administrator involving cardiac nurse to review and update policy and procedure who is more competent of this process. Approved by the governing board 12/27/11.</p>	11/17/2011			

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Q0161	<p>416.47(a) ORGANIZATION The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure the completeness of records for 5 of 13 patient medical records reviewed (pts. N1, N2, N3, N4 and N8).</p> <p>Findings: 1. review of patient medical records through out the survey process of 10/31/11 to 11/2/11 indicated: a. pts. N1, N2, N3 and N8 lacked indication on the "Informed Consent for Gastrointestinal Endoscopy" form (lower section of the page) that the physician "Reviewed/assessed history & physical note prior to procedure" (physician failed to check the box preceding this statement) b. without a time of authentication of the "Informed Consent for Gastrointestinal Endoscopy" form by practitioners, it cannot be determined that the authentication was prior to the procedure start time c. pt. N4 lacked completion on the "Informed Consent for Gastrointestinal Endoscopy" form of indication that the patient received: "Patient Rights", "Advance Directives" information, "Disclosure of Financial Interest...", "Moderate Sedation"</p>	O0161	<p>1a. the box for reviewed and assessed history and physical prior to procedure has been removed from consent form Physicians are now completing the history and physical in the electronic records G-med complete with date and time prior to procedure in the prep area. Clinical staff and medical staff reviewed at staff meeting mandated by state and federal regulation reviewed will not take patient to procedure room until authenticated documentation. Responsibility of each staff member and administrator, medical director with internal and external audit monitored randomly and external quarterly. Reviewed and approved at governing board meeting 12/27/11. 1c. Reviewed with staff the regulation at staff meeting of filling out the consent completely on checking appropriate boxes on financial investment, patient rights , physician documented in the computer reviewed and assessed history and physical. 3. Revised policy for medical record compositon #3. presented at the clinical and medical staff meeting on 12/1/11.</p>	12/01/2011			

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	<p>information, whether the patient to have an upper GI (gastrointestinal) procedure, a lower GI procedure, a possible biopsy and which provider was to be performing the procedure (all boxes preceding these items were left blank)</p> <p>2. at 2:30 PM on 11/1/11, interview with staff member NB indicated the charts as listed in 1. above were lacking completeness as noted</p> <p>3. a policy/procedure related to completeness of the medical record was requested during the survey and none was provided prior to exit</p>				

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Q0162	<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> <ul style="list-style-type: none"> (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 governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. <p>Based on patient medical record review and staff interview, the facility failed to ensure that documentation was clear that the pre anesthesia evaluation was performed prior to the surgical procedure for 12 of 12 patients with procedures performed (N1 through N8 and N10 through N13).</p> <p>Findings: 1. review of patient medical records for patients N1 through N8 and N10 through N13 through out the survey process of 10/31/11 to 11/2/11, indicated: a. the electronic document containing the pre anesthesia evaluation, performed</p>	Q0162	Clear documentation pre-anesthesia evaluation prior to the procedure captures the time in the electronic system. Noted but the current process captures as part of the procedure report. Updated the policy to state the physician will perform the patient pre-anesthesia evaluation (ASA) inclusive in the history and physical timed in the prep area and implement signature of orders. This will occur in the prep area prior capturing date, time and signature entry by the gastroenterologist. Nursing staff will visually confirm physician evaluation and documentation of time prior to taking the patient to the procedure room. ASA in the	11/11/2011			

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	<p>by the practitioner, is embedded within the operative report</p> <p>b. the electronic signature by the practitioner is timed after the procedure has ended and the patients have been discharged from the procedure room to the recovery area</p> <p>2. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the current computer system does not capture the time of the practitioner's pre anesthesia evaluation and selection of an ASA (American Society of Anesthesiologists) level prior to the operative procedure, as is required</p> <p>b. currently, the patient medical records for patients N1 through N8 and N10 through N13 have electronic documentation of a pre anesthesia evaluation by physicians that is timed after the procedures have been completed</p>		<p>room is part of the time out timed intraprocedure. IT nurse randomly audit compliance quarterly basis. Review with clinical and medical staff again on 1/5/12. Responsible administrator and medical director and support IT nurse monitoring of process.</p>		

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Q0201	<p>416.49(a) LABORATORY SERVICES</p> <p>If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter.</p> <p>Based on document request, observation and interview, the facility lacked a list indicating laboratory tests performed at the center and laboratory services provided by a certified laboratory, and lacked a policy/procedure for laboratory testing performed at the center and recorded in the patient record for 2 of 3 laboratory tests.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 10-31-11 at 0930 hours, staff #A1 was requested to provide a list of Point of Care (POC) tests and laboratory services provided by a certified laboratory and none was provided prior to exit. During a facility tour on 10-31-11 at 1530 hours, the following condition was observed in the nursing station of the center: a blood coagulation testing device 	Q0201	<p>1. Point of Care Tests done in the facility are Glucometer (glucose), INR (blood coagulation test) and HP one (Helicobacter Pylori test) with an updated policy/procedure and listed each POC. Updated document for each instrument involved and a log is maintained in separate books. POC staff competency update annually is part of the policy and procedure 11/17/11. Laboratory service used is Lab Corp which is a certified laboratory handles our specimens and on hand is certification with pathologist board credentials. Point of Care (POC) tests A. glucometer reading B. INR (blood coagulation test) C. HP one (Helicobacter Pylori test) 2. Certified Lab used Lab Corp #2 Policy and procedure written and in place for use of Coaguchek instrument in the facility. #3 Policy and procedure written and in place for using HP one (Helicobacter</p>	11/17/2011			

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	<p>" CoaguChek " . Staff #A1 was requested to provide a policy/procedure for use of the instrument at the center and none was provided prior to exit.</p> <p>3. During a facility tour on 10-31-11 at 1540 hours, the following condition was observed in the medication room refrigerator of the center: one box of " HPone Helicobacter Pylori test " containing 20 testing cassettes. Staff #A1 was requested to provide a policy/procedure for use of the instrument at the center and none was provided prior to exit.</p> <p>4. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the center lacked a list of POC tests and laboratory services provided by a certified laboratory and lacked a policy/procedure for the indicated POC tests.</p>		<p>Pylori) test in the facility. #4 same as #1 Infection control nurse will do a random audit process quarterly. Reviewed and approved at the governing board meeting 12/27/11 Enforced by the administrator, medical director and the infection control nurse.</p>		

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Q0221	<p>416.50(a)(1) NOTICE OF RIGHTS</p> <p>The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.</p> <p>Based on document review and interview, the facility failed to ensure that the patient rights document given to patients prior to the day of surgery included 9 of 14 required elements.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (reviewed 07-20-11) failed to include the requirement that the facility must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. The policy/procedure failed to identify the patient rights provided to each patient or responsible person.</p> <p>2. The document " Statement of a Patient ' s Bill of Rights " failed to indicate the following patient rights:</p> <p>a. The facility must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative</p>	O0221	<p>1. Patient rights policy was changed and the following was added to the policy: During the preop appointment USUALLY 3-5 DAYS PRIOR PROCEDURE the patient or patient's representative will RECEIVE a copy of Medical Consultants Endoscopy Center Patient Rights document. This document will be reviewed with patient or patient's representative prior to signing consentfor procedure with boxes checked.</p> <p>2a. The following was added to "Statement of a Patient's Bill of Rights" document. The patient has the right to receive a copy of statement Patient's Bill of Rights and have it explained to them prior to the date of the procedure.</p> <p>b. the website listed on Statement of a Patient's Bill of Rights was changed to http://www.cms.hhs.gov/ombudsman/resources.aspx. The following statement was added to the Statement of a Patient's Bill of Rights: the patient has the right to know the physician performing procedure has financial interest in Medical Consultants Endoscopy Center and patient may choose another health care facility.d. The following statement was added to</p>	12/01/2011			

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	<p>understands.</p> <p>b. The facility must provide the patient and/or the patient's representative with the following information whereby they may report complaints: Indiana State Department of Health Office of the Medicare Beneficiary Ombudsman The website identified on the document did not return a valid website address for the ombudsman.</p> <p>c. The facility must disclose, where applicable, physician financial interests or ownership in the facility. The document failed to identify that physicians had a financial interest in the center.</p> <p>d. The facility must provide the patient and/or their representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and (upon request) official State advanced directive forms. The facility must inform the patient or representative of the patient's rights to make informed decisions regarding the patient's care.</p> <p>e. The facility must notify the patient and/or their representative of the existence of a grievance procedure, including how to submit a complaint or grievance.</p> <p>f. The facility 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.</p> <p>g. 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 under applicable State health and safety laws by a court of proper jurisdiction. If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may</p>		<p>the Statement of a Patient's Bill of Rights The patient has the right to be informed of Medical Consultants Endoscopy Center's policy on Advanced Directives.e. Contact info was added to Statement of a Patient's Bill of Rights Grievances contact person: Linda Chastain Administrator 765-254-4763 800 S Tillotson Muncie Indian 47304. Agency of Healthcare Administrationf. The grievance policy was updated by stating the Medical Consultants Endoscopy will respond immediately to all grievances related to but not limited to mistreatment, neglect, verbal, mental, sexual or physical abuse or another serious allegations of harm end be documentedg,h and i The Statement of a patients Bill of Rights was ammended and added the following statements: The patient has the right to received care in a safe setting. The patient has the right to be free from all forms of abuse or harassemnt. The rights of the patient may be exercised by the person appointed under state law to act on patient's behalf or by any legal representative designated by the patient in accordance with the state law. Posted and updated @staff inservice 12/1/11</p>				

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	<p>exercise the patient's rights to the extent allowed by State law.</p> <p>h. The patient has the right to receive care in a safe setting, including, but not limited to, unwanted visitors and/or contaminated materials.</p> <p>i. The patient has the right to be free from all forms of abuse, neglect or harassment from staff, other patients, or visitors.</p> <p>3. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the facility patient bill of rights lacked 9 of 14 required elements.</p>						

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Q0222	<p>4166.50(a)(1)(i) NOTICE - POSTING In addition, the ASC must - Post the 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 document review, observation and interview, the facility failed to follow its policy/procedure to post written notice of patient rights in a conspicuous location for viewing by patients and responsible persons.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Patient Rights (reviewed 07-20-11) indicated the following: " A copy of the patients rights are posted in the patient area. " 2. During a facility tour on 10-31-11 at 1015 hours, a lack of posted patient rights was observed in the waiting and reception area of the center. 3. During an interview on 10-31-11 at 1100 hours, staff #A1 confirmed that the facility lacked the required posting. 	O0222	<p>Post written notice of patient rights in a conspicuous location was posted an updated draft of the Statement of a Patient's Bill of Rights in the Endoscopy Center Waiting Room approved by the governing board on 12/27/11, inserviced to the clinical staff on 1/5/12 and posted approved document and will be monitored by the administrator and medical director of the documents presence.</p>	12/01/2011
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Q0223	<p>416.50(a)(1)(ii) NOTICE - PHYSICIAN OWNERSHIP The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.</p> <p>Based on document review and interview, the facility failed to ensure a policy/procedure for notifying patients of physician financial interests or ownership in writing prior to the date of the procedure.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 10-31-11 at 0930 hours, staff #A1 was requested to provide the facility policy/procedure for notifying patients of physician financial interests or ownership and none was provided prior to exit. On 11-02-11 at 1730 hours, staff #A1 confirmed that the facility lacked the requested policy/procedure. 	Q0223	<p>Policy and procedure for notifying patients of physician financial interests or ownership in writing prior to date of procedure. Patients are notified in writing of physician financial interests and ownership ALWAYS during pre-op visit USUALLY 3-5 DAYS PRIOR and signature of notification confirmed on consent form WITH BOX CHECK ON NOTIFICATION but a policy and procedure was written to address the notifying of the patients of the physician financial interests or ownership. Review at the 12/1/11 inservice staff meeting. Monitored by the administrator and medical director with administrative secretary support update of the index with correct number paging in the policy and procedure book. Also added date to the witness signature on the consent form for clear identification of time. Audit as part of the medical record enforced by the administrator and medical director.</p>	12/01/2011			

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Q0225	<p>416.50(a)(3)(i), (v), (vi), (vii) SUBMISSION AND INVESTIGATION OF GRIEVANCES</p> <p>(i) 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.</p> <p>(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.</p> <p>(vii) The ASC must document how the grievance was addressed, as well as provide the patient 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 results of the grievance process, and the date the grievance process was completed.</p> <p>Based on document review and interview, the facility failed to ensure a complaint and grievance procedure that specifically addressed verbal and written complaints and grievances.</p> <p>Findings:</p> <p>1. The policy/procedure Grievance Policy for Patients (reviewed 07-20-11) lacked the following:</p> <p>a. criteria identifying how verbal and written complaints may be submitted and addressed including resolution at the time</p>	Q0225	Ensure complaint and grievance policy and procedure update to specifically addresses verbal and written complaints and grievances. If a patient or patient's representative voices a complaint to a staff member who will address the complaint to their ability and documented on nsg. notes. If unable to resolve complaint considered a grievance and reported to Linda Chastain Administrator verbally or written complaint submitted on designated form. Incident reported compliance issue at the medical staff meeting and part of the Safety report Governing	12/01/2011			

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	<p>of the complaint by staff present</p> <p>b. criteria indicating when a complaint will be considered a grievance</p> <p>c. timeframes for completing the review of allegations and providing a written response to the patient or representative that is not excessive</p> <p>d. criteria indicating how the facility would document the grievance process steps including date received, date completed and notification of the patient or representative</p> <p>2. The document Patient and/or Visitor Grievance Form (reviewed 07-20-11) failed to indicate that all grievances would be investigated.</p> <p>3. During an interview on 11-02-11 at 1730, staff #A1 confirmed that the grievance policy lacked the provisions indicated above.</p>		<p>Board . Criteria detailed when a complaint becomes a grievance in policy and procedure. Filed, date and reported with documented follow up interviewing patient and or representative. Documented date and time patient and or representative was notified of investigation and handling of grievance. Grievance policy and procedure and grievance form reviewed and approved medical staff meeting and Governing Board on 12/27/11. Inservice with clinical staff 1/5/12.</p>		

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Q0226	<p>416.50(a)(3)(ii), (iii), (iv) GRIEVANCES - MISTREATMENT, ABUSE, NEGLECT</p> <p>(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.</p> <p>(iii) All allegations must be immediately reported to a person in authority in the ASC.</p> <p>(iv) Only substantiated allegations must be reported to the State authority or the local authority, or both.</p> <p>Based on document review and interview, the policy/procedure Grievance Policy for Patients failed to identify how allegations including mistreatment, neglect and abuse would be fully documented and failed to identify how the facility would report substantiated allegations to a state and/or local authority.</p> <p>Findings:</p> <p>1. The policy/procedure Grievance Policy for Patients (reviewed 07-20-11) failed to indicate how allegations of mistreatment, neglect, and abuse will to be documented including time and date of occurrence, the names of all individuals involved, and the specific actions and events that are alleged to have occurred that may be considered mistreatment, neglect, or abuse. The policy/procedure failed to indicate how the facility would document provisions ensuring patient safety while</p>	Q0226	<p>Policy and procedure Grievance for patient to identify how allegations including mistreatment, neglect and abuse will be detailed documented and report allegations to state and local authority with time, date of occurrence, names of patient and representative involved, specification and events alleged to have occurred considered mistreatment, neglect or abuse. Document provisions ensure pateint safety while allegations are investigated. Reporting process to agencies contacted, and updated with descriptive process of the policy and procedure reviewed and approved by the medical staff and approved at the Governing Board meeting 12/27/11. Inservice staff on 1/5/12. Responsibility of the administrator and medical director enforce this process with detailed reporting at the medical staff meeting and governing board. Ongoing education of clinical staff of this process with written document.</p>	12/02/2011			

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	<p>allegations are investigated. The policy/procedure lacked a description of its reporting process including what agencies will be contacted (local police, state attorney general, etc) for substantiated allegations.</p> <p>2. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedure lacked the requirements indicated above.</p>			

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Q0227	<p>416.50(b)(1)(i) RESPECT - PROPERTY & PERSON The patient has the right to - Exercise his or her rights without being subjected to discrimination or reprisal.</p> <p>Based on document review, the facility failed to ensure a policy/procedure that a patient or their representative may exercise their rights without fear of reprisal.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (reviewed 07-20-11) failed to indicate that a patient may exercise their rights without being subjected to discrimination or reprisal.</p> <p>2. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedure lacked the indicated requirement.</p>	O0227	<p>Policy and procedure Patient Rights updated indicate patient may exercise their right without being subjected to discrimination or reprisal posted and updated at staff inservice 12/1/11. Ensure monitoring by administrator and medical director with incident documentation of complaints or grievances. Documented on consent patient was informed and medical record monitoring randomly quarterly of chart.</p>	12/01/2011	

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Q0230	<p>416.50(b)(2), 416.50(b)(3) EXERCISE OF RIGHTS BY OTHERS (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.</p> <p>Based on document review and interview, the facility failed to ensure a policy/procedure for the exercise of patient rights by the legal representative where the patient is determined to be incompetent by a court of law or otherwise where a patient may have designated a legal representative to exercise the patient's rights.</p> <p>Findings:</p> <p>1. The facility policy/procedure Patient Rights (reviewed 07-20-11) lacked a provision for the exercise of patient rights by the legal representative where the patient is determined to be incompetent by a court of law or otherwise where a patient may have designated a legal representative to exercise the patient's rights.</p>	Q0230	<p>Group of three non financial interest of licensed physician are provided to the center for utilization review of our practicing physician. Utilization review at the medical staff meeting and governing board minutes amending more detailed documentation and maintaining individual worksheet of the 3 physician reviews of each medical records on the practicing physicians. Governing Board meeting approved ongoing appointment of the 3 same physician reviewing the practicing physicians 12/27/11. Administrator and medical director responsible for detailed documentation of activity existing but not well documented vague. Document minutes in a timely manner and log.</p>	12/01/2011	

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Q0231	<p>2. During an interview on 11-02-11 at 1730 hours, staff #A2 confirmed the policy/procedure lacked the indicated provision.</p> <p>416.50(c)(1) PRIVACY The patient has the right to - Personal privacy</p> <p>Based on document review and interview, the facility failed to ensure a policy/procedure indicating the patient right to personal privacy.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (reviewed 07-20-11) lacked a provision for the patient right to personal privacy.</p> <p>2. During an interview on 11-02-11 at 1730, staff #A1 confirmed that the policy/procedure lacked the provision indicated.</p>	O0231	<p>The following statement was added to the Patients Rights Policy: The patient has the right to personal privacy. Reviewed with medical and clinical staff on 12/1/11 and approved by the governing board 12/27/11 and be part of Q0222 posted 1/6/12. Monitored by administrator and medical director.</p>	12/01/2011	

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Q0232	<p>416.50(c)(2) SAFETY [The patient has the right to -] Receive care in a safe setting</p> <p>Based on document review and interview, the facility failed to ensure a policy/procedure for the patient right to receive care in a safe setting and deter unwanted visitors.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (reviewed 07-20-11) lacked a provision for the patient right to receive care in a safe setting and deter unwanted visitors.</p> <p>2. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedure lacked the indicated provision.</p>	Q0232	<p>Updated and reviewed policy and procedure on Patient Bill of Rights detailed patient right to receive care in a safe setting and deter unwanted visitor. The patient has the right to be free from all forms of abuse or harassment. Posted and updated at staff inservice 12/1/11. Responsibility administrator, medical director and safety nurse compliance to this policy with incident reporting, verbal and written documentation and follow up with review at medical staff and governing board. Randomly monitoring detail quarterly</p>	12/01/2011			

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Q0233	<p>416.50(c)(3) SAFETY - ABUSE/HARASSEMENT [The patient has the right to -] Be free from all forms of abuse or harassment</p> <p>Based on document review and interview, the facility failed to ensure a policy/procedure for the patient right to be free from abuse, neglect or harassment; whether from staff, another patient or other persons.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (reviewed 07-20-11) lacked a provision for the patient right to be free from abuse, neglect, or harassment.</p> <p>2. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedure lacked the indicated provision.</p>	O0233	The following statement was added to the Patient Rights policy: The patient has the right to be free from all forms of abuse or harassment. Inservice on 12/1/11 and approved by the governing board 12/27/11 and will be posted 1/6/12 after 1/5/12 staff inservice. Monitored by the administrator and medical director.	12/01/2011			

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Q0242	<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 review of policies and procedures and staff interview, the infection control practitioner failed to establish specific infection control standards or goals with measurable indicators, and failed to implement its policy related to follow up with physicians for any complications or infections post procedure.</p> <p>Findings: 1. at 10:15 AM on 11/1/11, review of the "Infection Control Program" (pages 235 and 236) with an Effective date of 01-3-04 and a most recent reviewed/approved date of 4-28-11, indicated: a. this document is general and vague and does not indicate what the facility will monitor or measure in relation to infection prevention and control b. the document does not present any indicators or goals which would indicate that the facility had determined an effective ongoing infection control plan had been developed</p>	00242	<p>1a. Infection Control Program is being re-evaluated and expanded to meet current guideline. The Infection Control Nurse will begin monitoring 2 projects at the start of 2012. The first Infection Control focus project will be related to our patient Infection/Complication Report. The second Infection Control focus project will be related to our cleaning process in the procedure rooms. This targeted group will be the procedure room personel including the housekeeper. These projects are currently being developed to form specific and measureable goals. 1b. As stated above, the Infecnon Control Program is currently being revamped to include quality indicators and specific goals to meet this criteria. Research regarding infection control programs is being completed by Infection Control Nurse to meet these requirements. 2a. This policy Infection/complication report is being ammended to reflect current policy. The infection occurrence will no longer be recorded as a complication in</p>	12/02/2011			

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	<p>2. at 10:30 AM on 11/1/11, review of the policy "Infection/Complication Report" (pg 58) with an effective date of 01-3-04, and a most reviewed/approved date of 4-28-11, indicated:</p> <p>a. under "Policy", it reads: "infection occurrence will be recorded as a complication in the computer system under "Occurrences"..."</p> <p>b. under "Procedure", it reads: "1. In the first week of each month, the scheduler will send the physician a letter asking for information concerning any complications which occurred after the patient left the facility. These complications could include infection, hemorrhage, severe nausea, perforation, etc...3. The infection log will be reviewed b the Quality Improvement Committee and reported to the Governing Board..."</p> <p>3. interview with staff member ND at 1:00 PM on 11/2/11 indicated:</p> <p>a. this staff member was asked to be the ICP (infection control practitioner) in the summer of 2010, but did not begin any of the duties of the ICP until May, 2011</p> <p>b. this staff member was unaware of the policy related to physician contact post procedure for information related to any complications or infections</p> <p>c. at this time, the procedure known by</p>		<p>the computer system under occurrences. This statement has been removed from our policy. The new ploicy states: beginning of each month patient care coordinator of MCEC will forward a list from Gmed all patients physician scoped the previous month. Each physician will document any infection/complication which occurred after the patient was discharged from our facility. If an occurrence, follow up documentation and/or follow up office visit will be required and part of the chart. The infection/complication report will be reviewed by the Quality Improvement committee and reported to the governing board quarterly. 3a. ICP duties actively and continually working on Infection Control projects at MCEC since 10/31/11-11/2/11 survey. This included educational research, updating policies and determing quality Infection Control projects for the year 2012. A more consistent effort and time allotment has been achieved and will continue to be ongoing with Administrator support of assigning allotted time weekly. 3b. All clinical and medical staff member of MCEC are informed of the updated Infection/Complication report, and the policy has been made available for review.3c. Physicians responsible for reporting occurrences. Each</p>				

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	<p>this staff member, in obtaining information related to possible post procedure infections is to instruct patients, as a part of their discharge instructions, to call the facility if they develop a fever</p> <p>4. interview with staff member NE at 3:40 PM on 11/2/11 indicated:</p> <p>a. after checking with the scheduler, it was found that the policy/procedure for sending a letter to the physicians, related to post procedure complications and infections, is not occurring</p>		<p>patient given a list of "warning signs" and contact information 4a As per previous information The Infection Complication Report Policy has been modified to reflect the scheduler is not sending a letter, but the MCEC Patient Care Coordinator is forming this document. Inservice with staff on 1/5/12</p>		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
Q0245	<p>416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>Based on policy and procedure review, employee health file review and staff interview, the infection control committee and infection control practitioner failed to ensure a safe, effective infection control plan related to communicable disease history was determined for 4 of 6 staff members (P1, P3, P4 and P5).</p> <p>Findings: 1. at 9:30 AM on 11/2/11, review of the policy "General Infection Control Practices for MCEC" (Medical Consultants Endoscopy Center), indicated: a. under "Policy", in item "1. Personnel", it reads: "...All personnel must comply with all Employee Health Services health requirements related to immunizations, serologic testing, PPD (purified protein derivative) Mantoux Skin Testing (at BMH) [Ball Memorial Hospital] and respirator fit testing..."</p> <p>2. at 11:05 AM and 2:00 PM on 11/2/11, review of employee health file reviews for</p>	O0245	<p>1.a General Infection Control Practices for MCEC under "Policy" item 1. Personnel: The following changes were made to this policy. All personnel must comply with all medical consultants endoscopy center health requirement related to immunizations, serologic testing and PPD mantoux skin testing, yearly TB testing will be required and provided by medical consultants. Respirator fit testing is not applicable to nursing care at MCEC and was deleted from this policy. 2. Staff members self reporting history of varicella- all MCEC employees who are providing direct patient care will be having serology testing completed. This will be done to confirm immunity and staff without immunity will be revaccinated per guidelines. Self reporting of these diseases will no longer be valid source of documentation. These changes are supported in our Policy and Procedure Employee/Physician Statement of Health. 3a. Our policy "General Infection Control Practices for MCEC will be</p>	12/02/2011			

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	<p>staff members P1, P3, P4 and P5 indicated all had self reported a history of Varicella</p> <p>3. at 1:00 PM on 11/2/11, interview with staff member ND, the infection control practitioner, indicated:</p> <p>a. the policy listed in 1. above does not specifically address what communicable diseases new employees will be required to report a history of</p> <p>b. the policy listed in 1. above is not specific as to how the communicable diseases should be reported for history, such as: a positive titer, documentation of immunization, etc.</p> <p>c. it was unknown by this staff member what the CDC (centers for disease control/prevention) recommended for communicable disease history in health care workers</p> <p>d. the infection control plan and policies are incomplete in relation to communicable disease standards for employees</p>		<p>ammended to address what new employees will be required to report a history of relation to communicable diseases. Information was obtained from the CDC on Nationally Notifiable Infection condition. This extensive list of health conditions will be reviewed by each MCEC employee with an yes or no response and each yes will be addressed by the Admin. with confidentiality. 3b. Stated above employee will self report on CDC Notifiable Infectious Condition. and per policy and procedure self reporting not valid for Hepatitis B or varicella need required vaccination or immunity proof. 3c. CDC National Notifiable Infectious Condition is now in our Infection Control book to reflect requirement. #d. Infection Control Policy and Procedure are in the process of becoming more detailed and complete related to communicable disease standard. Reviewed with staff individually the outcomes and updated policy with 12/15 personnel completed and ongoing monitoring Infection Control Nurse of immunization records with administrator responsibility support process. Reporting of process to governing board details quarterly.</p>		

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Q0261	<p>416.52(a)(1) ADMISSION ASSESSMENT Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy.</p> <p>Based on policy and procedure review, patient medical record review and staff interview, the facility failed to ensure that documentation was clear that a history and physical evaluation was performed prior to the surgical procedure for 12 of 12 patients with procedures performed. (N1 through N8 and N10 through N13)</p> <p>Findings: 1. review of the policy and procedure "History and Physical of Patient" at 11:30 AM on 11/1/11 indicated: a. under "Policy", it reads: "All patients seen at Medical Consultants Endoscopy Center will have a completed history and physical on the chart before the procedure begins..."</p> <p>2. review of patient medical records for patients N1 through N8 and N10 through N13 through out the survey process of 10/31/11 to 11/2/11, indicated: a. the electronic document containing the medical history and physical, performed by the practitioner, is</p>	00261	<p>Clear that history and physical evaluation performed prior to procedure 2b. Physician are now performing a history and physical in the prep area prior to the procedure with captured electronically with date and time attached. 3a and b There is now a policy that states the pre anesthesia evaluation, patients history and physical and physicians orders are all captured a the same time in the prep area prior to the procedure as noted in the past but the electronic system failed to capture date and time The physician signature is captured with the physician orders in the electronic records. Reviewed and approved governing board meeting 12/27/11 Ongoing random audit of IT nurse weekly then quarterly</p>	12/01/2011			

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	<p>embedded within the operative report</p> <p>b. the electronic signature by the practitioner is timed after the procedure has ended and the patients have been discharged from the procedure room to the recovery area</p> <p>3. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the current computer system does not capture the practitioner's review, electronically, of the patient's history and physical prior to the operative procedure as is required</p> <p>b. currently, the patient medical records for patients N1 through N8 and N10 through N13 have electronic authentication by physicians that is timed after the procedures have been completed</p>				

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Q0266	<p>416.52(c)(2) DISCHARGE - ORDER [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure that 1 of 1 transfer patients had an order for transfer to an acute care facility (pt. N9).</p> <p>Findings:</p> <ol style="list-style-type: none"> at 9:30 AM on 11/1/11, review of the transfer record of pt. N9 indicated there was no physician order to transfer the patient at 2:30 PM on 11/1/11, interview with staff member NB indicated the nursing staff failed to obtain, or document, a physician order to transfer pt. N9 to the acute care hospital 	O0266	<p>Ensure each patient has an discharge order signed by the physician for transfer. Revised policy and nursing staff needs order authenticated by physician. Reviewed and inservice clinical and medical staff order with in 30 minutes and incident reporting Q/A audit safety officer, adminstrator and medical director monitoring at time of incident than randomly quarterly audit of process. Reviewed and approved by the board 12/27/11. Electronic default was removed so each nursing note has to be populated prevent error automatic discharge to home.</p>	12/01/2011			

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S0148	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c) (4)</p> <p>(c) The governing body shall do the following:</p> <p>(4) Require that the chief executive officer designate in writing an administrative officer to serve during his or her absence.</p> <p>Based on document review and interview, the chief executive failed to clearly indicate in writing who would be in charge when the chief executive officer was not present.</p> <p>Findings:</p> <p>1. The policy/procedure Absence of CEO/Administrator/DON (reviewed 07-20-11) failed to indicate who would be in charge when the administrator was unavailable.</p> <p>2. The policy/procedure Absence of Executive Officer (reviewed 08-10-11) identified three staff and failed to indicate a hierarchy or primary and first alternate in command when the administrator was unavailable.</p> <p>3. During an interview on 11-02-11 at</p>	S0148	The policy and procedure was ammended in the manual. The policy and procedure list a hierarchy with primary than first alternate in the absence of the CEO/Administrator. Reviewed and approved with medical director. Informed staff of the policy and procedure.	11/14/2011			

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	1730 hours, staff #A1 confirmed the policy/procedures failed to indicate who would serve as the responsible person for the center.				

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S0153	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on employee file review and staff interview, the facility failed to provide documentation of orientation for both the full time housekeeper and the substitute housekeeper (P4 and P6).</p> <p>Findings:</p> <p>1. at 11:05 AM on 11/2/11, review of personnel files indicated:</p> <p>a. staff member P4 lacked any indication in the employee file of orientation as the back up or substitute housekeeper</p> <p>b. staff member P6 lacked any indication in the employee file of housekeeper orientation</p> <p>2. interview with staff members NA and ND at 1:10 PM on 11/2/11, indicated:</p> <p>a. staff member P4 is the "back up" to the regular housekeeper when they are sick or on vacation</p> <p>b. there is no documentation of</p>	S0153	<p>Documentation of orientation for the housekeeper and the substitute housekeeper (endocopy technician) filed in employee file. Updated job description and orientation policy and procedure for housekeeping with detailed duties in the center. Reviewed and documented with staff. Responsibility of the administrator job reflect detailed duties of the center not the adjoining clinic and this deficiency of orientation to detail will be random audit of the cleaning process by ICP. All job description and orientation updating and to be completed by 1/30/12 for the center and review all employee files with a check sheet noting all data currently filed.</p>	12/02/2011

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	orientation to housekeeping duties for either staff member P4 or P6			

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S0156	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on employee file review and staff interview, the facility failed to provide a job description to the infection control practitioner (ICP), failed to provide the substitute housekeeper with a job description, and failed to ensure that the housekeeper's job description included the duties in cleaning the surgery center's procedure rooms and pre/post operative areas.</p> <p>Findings: 1. at 11:05 AM on 11/2/11, review of personnel files indicated: a. staff member P3 was the designated ICP and lacked having a copy of the position job description for an infection control practitioner in the personnel file</p>	S0156	<p>Job description for the infection control nurse and housekeeper job description with detailed duties listed in the cleaning of procedure room, prep area and the recovery area etc. 1a job description for the infection control nurse is completed. 1b. Job description for the housekeeper is updated detailed to the surgery center. 1c. Job description details expected cleaning process of the surgery center areas, pre/post, instrument/decontamination area and procedure rooms. 2c,d,e this "back up " position for housekeeper is endoscopy technican. Infection control nurse and the housekeeper job description reviewed with the involved staff 1/5/12 along with policy and procedure. Ongoing</p>	12/01/2011			

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	<p>b. staff member P4 had a job description for an "Endoscopy Technician", but lacked a copy of the job description as housekeeper</p> <p>c. staff member P6 had a job description titled "Housekeeper", that lacks any instruction related to expectations in cleaning the surgery center areas, such as: pre/post op areas, the instrument decontamination room, and the procedure rooms</p> <p>2. interview with staff members NA and ND at 1:10 PM on 11/2/11, indicated:</p> <p>a. staff member P3 was asked to be ICP during the summer of 2010, but didn't begin those duties until June 2011</p> <p>b. staff member P3 has not been provided a copy of the job description that would inform them of duties of the position of ICP</p> <p>c. staff member P4 is the "back up" to the regular housekeeper when they are sick or on vacation</p> <p>d. there is no job description, related to housekeeping duties, in the employee file for staff member P4</p> <p>e. the job description for a housekeeper for staff member P6 addresses the physician offices and exam rooms, not the surgery center areas</p>		<p>monitoring monthly of the housekeeping process will be responsibility of the infection control nurse than quarterly with support of the administrator for availability of time.</p>				

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S0162	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (G)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel, who provide direct patient care.</p> <p>Based on employee file review and staff interview, the chief executive officer failed to implement the job description requirements for 1 of 1 instrument tech files reviewed. (P4)</p> <p>Findings: 1. at 11:05 AM on 11/2/11, review of personnel files indicated: a. staff member P4 was an instrument technician hired 10/20/03 b. the job description in the P4 personnel file was titled "Endoscopy Technician" c. the "Endoscopy Technician" job description listed under "Qualifications": "A. High School Graduate, BCLS (basic cardiac life support), if not BCLS willing to take training within the first six months..." d. the CPR (cardiopulmonary</p>	S0162	Endoscopy staff member is viewing video and reading materials and scheduled for final test on CPR 1/13/12. Staff member Endoscopy Technician meeting job requirement assisting in the procedure room. CPR expired 10/31/11 and the Endoscopy Technician is not scheduled to staff endoscopy in the assisting role until this is completed. Endoscopy Technician staffs processing scopes only. Responsibility of administrator to schedule this certification sooner to meet deadline.	12/02/2011			

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	<p>resuscitation) card in the personnel file of staff member P4 had a 10/31/11 expiration date</p> <p>2. interview with staff member ND at 1:10 PM on 11/2/11 indicated:</p> <p>a. the facility staff all renewed their CPR/BCLS in October, but staff member P4 was absent that day</p> <p>b. CPR is required, per the job description, for staff member P4</p> <p>c. staff member P4 has let their CPR expire and was still currently working within the facility</p>				

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S0182	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (O)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(O) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.</p> <p>Based upon document review and interview, the center failed to document the performance of an annual disaster preparedness plan including an evaluation of the outcome to be shared with center staff.</p> <p>Findings:</p> <p>1) On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation of an annual disaster preparedness exercise and none was provided prior to exit.</p> <p>2) During an interview on 11-01-11 at 1430 hours, staff #A1 indicated that the center lacked documentation of an annual disaster exercise for 2010-2011.</p>	S0182	<p>Annual disaster preparedness plan established for 2012 listed and inservice on 1/5/12 including an evaluation of the outcome will be shared with center staff. Local agency contacted for center participation. Administrator responsibility on reporting the plan with documentation of staff knowledge and recorded outcomes in monthly meetings.</p>	12/01/2011	

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S0226	<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 facility failed to maintain a list of all contracted services, including the scope and nature of services provided, for 12 services.</p> <p>Findings:</p> <p>1. On 10-31-11 at 0930 hours, a list of all contracted services was requested from staff #A1, and no list was provided to review prior to exit from the facility.</p> <p>2. Review of facility documentation indicated that biohazardous waste disposal was provided by V 1, biomedical engineering was provided by V 2, commercial door service was provided by V 3, endoscope support was provided by V 4, fire detection and suppression was provided by V 5, heating/air conditioning service was provided by V 6, laboratory services were provided by V 7, laundry service was provided by V 8, medical gas and vacuum pump service was provided by V 9, pest control service was provided by V 10, pharmacy consulting was provided by V 11, and</p>	S0226	An updated list of contracted services was reformatted including the scope and nature of the service with dates and outcomes on a flow sheet monitoring QA including the Steri-cycle, Trimedix, Custom Ultrasonics, Deem, Deckeroff, Pharmacist, Orkin, Labcorp, Simplex Grinnell, Superior Linen and Olympus. Implementing the updates of this list enforced by the administrator, safety nurse and medical director. The flow sheet will identify risk factor and/or incidence. Quarterly reporting to the Governing Board.	11/21/2011			

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	ultrasonic cleaner support service was provided by V 12. 3. On 11-02-11 at 1730 hours, staff #A1 confirmed that the center failed to maintain a list of contracted services.				

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S0230	<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 body failed to assure that utilization review was provided by a group of three (+) licensed physicians without financial interest in the center.</p> <p>Findings:</p> <p>1. On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation of utilization review committee meetings or activity for 2011 and no documentation was provided prior to exit.</p> <p>2. During an interview on 11-02-11 at 1145 hours, staff #A6 indicated that MD 6, MD7, and MD8 were conducting utilization review for the center and staff #A1 would provide documentation. No</p>	S0230	<p>Group of three non financial interest of licensed physician are provided to the center for utilization review of our practicing physician. Utilization review at the medical staff meeting and governing board minutes amending more detailed documentation and maintaining individual worksheet of the 3 physician reviews of each medical records on the practicing physicians. Governing Board meeting approved ongoing appointment of the 3 same physician reviewing the practicing physicians 12/27/11. Administrator and medical director responsible for detailed documentation of activity existing but not well documented vague. Document minutes in a timely manner and log.</p>	11/30/2011			

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	<p>documentation indicating that specific medical records were reviewed for each credentialed practitioner (or identifier) on a particular date by a specific MD (6, 7, 8) was provided by staff #A1 prior to exit.</p> <p>3. Review of Governing Board meeting minutes for 2010 and 2011 failed to indicate board appointment of three physicians without financial interest in the center.</p> <p>4. During an interview on 11-02-2011 at 1730 hours, staff #A2 confirmed that no supporting documentation to confirm compliance of utilization review was available.</p>				

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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the facility failed to evaluate 1 direct service (medical records) 12 contracted services (biohazardous waste disposal, biomedical engineering services, commercial door service, endoscope service, fire detection and suppression service, heating/air conditioning service, laboratory, laundry, medical gas and vacuum pump service, pest control, pharmacy consulting, and ultrasonic cleaner service) through the Quality Assessment and Performance Improvement (QAPI) program.</p> <p>Findings:</p> <p>1. Review of facility documentation indicated that biohazardous waste disposal was provided by V 1, biomedical engineering was provided by V 2, commercial door service was provided by V 3, endoscope support was provided by</p>	S0310	<p>Updated logging format and policy and procedure to review and evaluate listed contracted services and arrangement of RHIT on 11/17/11 contracted begin established audit 2012 outside agency with QA monitoring with detailed reporting at medical staff and governing board meetings. Responsibility of administrator and medical director involvement in the reporting structure. The new format will assist in better documentation.</p>	11/17/2011			

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	<p>V 4, fire detection and suppression was provided by V 5, heating/air conditioning service was provided by V 6, laboratory services were provided by V 7, laundry service was provided by V 8, medical gas and vacuum pump service was provided by V 9, pest control service was provided by V 10, pharmacy consulting was provided by V 11, and ultrasonic cleaner support service was provided by V 12.</p> <p>2. On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation of ongoing QA for medical records and all contracted services including reporting to medical staff and governing board and no documentation was provided prior to exit.</p> <p>3. The Quality Assessment Program (approved 9-21-11) indicated the following: "The QA Program ... will include ongoing and incident based monitors. Ongoing monitors will include ... 4. Vendor performance [and] 9. Medical records."</p> <p>4. During an interview on 11-02-11 at 1210 hours, staff #A1 confirmed that the center did not contract with a medical records consultant or employ an Registered Health Information Technician</p>			

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	(RHIT) or Registered Health Information Administrator (RHIA) for the medical records maintained at the center. 5. On 11-02-11 at 1730 hours, staff #A1 confirmed that the center failed to follow its policy/procedure for the QA program to document ongoing monitoring for medical records and 12 contracted services.				

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S0328	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(b)</p> <p>(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:</p> <p>(1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.</p> <p>Based on document review and interview, the facility failed to address deficiencies identified by the quality assessment/performance improvement (QAPI) program for the medical records service.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Assurance - Medical Records (reviewed 09-21-11) indicated the following: " The QA Coordinator (DON) will gather data that is to be reviewed ... from [the] medical record consultant report. "</p> <p>2. Administrative documentation dated 07-20-10 indicated that the facility lacked</p>	S0328	Internal audit by nursing staff will be assigned monthly as well as quarterly with contracted outside RHIT hired due to the medical record director of the corporation failed to obtained the requested cerification. QAPI monitoring will review staff and external contracted RHIT report will identify deviations at the medical staff meeting reporting and governing board approved the outside RHIT Responsibility of the administrator to governing board in compliance of this deviation. We will consult with the RHIT on the evaluation of update version of our EMR and/or new vendor.	12/01/2011			

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	<p>a registered health information administrator (RHIA) or a registered health information technologist (RHIT) and indicated that the center would pursue using a consultant to comply with state law 410 IAC 15-2.5-3(b)(1).</p> <p>3. On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation of medical records services being directed by an RHIA or RHIT qualified individual or supervised by an RHIA/RHIT consultant and no documentation was provided prior to exit.</p> <p>4. On 11-02-11 at 1210 hours, staff #A4 confirmed that the center did not directly employ or contract with an RHIA or RHIT qualified individual for the medical record services at the center.</p> <p>4. On 11-02-11 at 1730 hours, staff #A1 confirmed that the center had failed to take action in response to the identified deficiency and document the effectiveness of the consultant by ongoing evaluation of the services through the QAPI program.</p>				

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S0332	<p>410 IAC 15-2.4-2.2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(1)</p> <p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the center: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained.</p>			

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	<p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:</p> <p>(AA) Catheters.</p> <p>(BB) Drains and other specialized tubes.</p> <p>(CC) Infusion pumps.</p> <p>(DD) Ventilators.</p> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <p>(i) Infant discharged to the wrong person.</p> <p>(ii) Patient death or serious disability associated with patient elopement.</p> <p>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to</p>			

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	<p>the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.</p> <p>(D) The following care management events:</p> <p>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:</p> <p>(AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration.</p> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug=drug interactions for which there is known potential for death or serious disability.</p> <p>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</p> <p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <p>(AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy.</p> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is</p>			

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	<p>progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the center.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <p>(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <p>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:</p> <p>(AA) contains the wrong gas; or (BB) is contaminated by toxic substances.</p> <p>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</p> <p>(iv) Patient death or serious disability associated with a fall while being cared for in the center.</p> <p>(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.</p> <p>(F) The following criminal events:</p> <p>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</p> <p>(ii) Abduction of a patient of any age.</p> <p>(iii) Sexual assault on a patient within or on the grounds of the center.</p> <p>(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</p>			

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	<p>Based on document review and interview, the Quality Assessment and Performance Improvement (QAPI) program failed to include the reportable events identified by state law 410 IAC 15-2.4-2.2 Reportable Events.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 10-31-11 at 0930, staff #A1 was requested to provide documentation how reportable events were included in the QAPI program and none was provided prior to exit. 2. The policy/procedure Quality Improvement - Monitors (reviewed 09-21-11) failed to indicate reportable events would be included in the program monitors. 3. The policy/procedure Reportable Diseases and Conditions (reviewed 4-28-11) failed to indicate any of the reportable events indicated by state law identified above. 4. Review of undated, unlabeled documents titled Third Quarter July-Sept 2011 failed to indicate a category or section titled Reportable Events with other quality services and functions. 5. During an interview on 11-02-11 at 	S0332	Reportable events policy and procedure updated and filed correctly in the index. Reportable diseases and condition detailed in the QA minutes medical staff meetings and the governing board minutes. Responsibility of administrator and medical director reporting listed in minutes more detailed not to be vague.	12/01/2011			

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	<p>1730, staff #A1 confirmed that the QAPI program lacked monitoring and reporting for the reportable events indicated by state law.</p> <p>4. On 1-02-11 at 1730 hours, staff #A1 confirmed that the center lacked a policy/procedure for</p>				

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S0334	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p>			

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	<p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on document review and interview,</p>	S0334	Reportable events policy and	12/01/2011	

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	<p>the center lacked a process for reporting events identified by state law 410 IAC 15-2.4-2.2 (a)(1) Reportable Events that were identified by the Quality Assessment and Performance Improvement (QAPI) program to have occurred at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 10-31-11 at 0930, staff #A1 was requested to provide documentation of the process for reporting events to the Indiana State Department of Health (ISDH) and/or other municipal, state or federal agency and none was provided prior to exit. 2. The policy/procedure Reportable Diseases and Conditions (reviewed 4-28-11) failed to indicate the process identified be state law 410 IAC 15-2.4-2.2 (a)(2) for reporting events to the ISDH. 3. During an interview on 11-02-11 at 1730, staff #A1 confirmed that the QAPI program lacked a policy/procedure for reporting events to the ISDH. 		<p>procedure needed updated and filed correctly in index of the policy and procedure manual QA reporting listed in clinical and medical staff minutes and governing board minutes more detailed not vague to support law on reporting structure. If no report needs noted in minutes. The facility does file the reportable event form to the state. Responsibility of administrator, medical director and infection control nurse.</p>		

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S0404	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(b)</p> <p>(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p> <p>Based on review of policies and procedures and staff interview, the infection control practitioner failed to establish specific infection control standards or goals with measurable indicators for an effective ongoing infection control plan. The infection control practitioner also failed to implement the facility policy related to follow up with physicians for any complications or infections post procedure.</p> <p>Findings: 1. at 10:15 AM on 11/1/11, review of the "Infection Control Program" (pages 235 and 236) with an Effective date of 01-3-04 and a most recent reviewed/approved date of 4-28-11, indicated: a. this document is general and vague and does not indicate what the facility</p>	S0404	<p>ICP1a. Infection Control Program is being re-evaluated and expanded to meet current guideline. The ICP will begin monitoring 2 projects Jan. 2012. the first project will be our patient Infection Complicaiton Report. The second project will be related to our cleaning process int he procedure rooms. This targeted group is the procdure room personnel and housekeeper. Ongoing development to form specific and measureable goals. Approved at the medical staff and governing board meeting 12/27/11. 1b. As stated above, the Infection Control Program is currently being revamped to include qulity indicators and specific goals to meet this criteria. Research regarding infection control programs is being completed by the ICP to satisfy these requirements.2a. This policy Infection/complication report is currently being ammended to reflect our current</p>	12/01/2011			

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	<p>will monitor or measure in relation to infection prevention and control</p> <p>b. the document does not present any indicators or goals which would indicate that the facility had determined an effective ongoing infection control plan had been developed</p> <p>2. at 10:30 AM on 11/1/11, review of the policy "Infection/Complication Report" (pg 58) with an effective date of 01-3-04, and a most reviewed/approved date of 4-28-11, indicated:</p> <p>a. under "Policy", it reads: "infection occurrence will be recorded as a complication in the computer system under "Occurrences"..."</p> <p>b. under "Procedure", it reads: "1. In the first week of each month, the scheduler will send the physician a letter asking for information concerning any complications which occurred after the patient left the facility. These complications could include infection, hemorrhage, severe nausea, perforation, etc...3. The infection log will be reviewed b the Quality Improvement Committee and reported to the Governing Board..."</p> <p>3. interview with staff member ND at 1:00 PM on 11/2/11 indicated:</p> <p>a. this staff member was asked to be the ICP (infection control practitioner) in the</p>		<p>policy. The infection occurrence will no longer be recorded as a complication in the computer system under 'occurrences'. This statement removed from our policy and procedure. The new policy states: The patient care coordinator of MCEC will forward a list from Gmed of all patients that each physician scoped the previous month. Each physician will then document any infection/complication which occurred after the patient was discharged from our facility. If a complication/infection occurred after patient discharged , follow up documentation such as hospital discharge summary or follow up care. Reviewed by the Quality Improvement committee and reported to the medical staff and the governing board quarterly. ICP actively and continually working on Infection Control projects at MCEC since 10/31/11 survey. This has included documented education, research, updating policies and dermering quality infection control projects for the year 2012. A more consistent effort and time allotment has been achieved with the Administrator support of weekly scheduled time for infection control process and including reporting to the medical staff. 3b Clinical and medical staff educated on the updated Infection/Complication Report and the policy has been updated and reviewed. Approved at the</p>				

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	<p>summer of 2010, but did not begin any of the duties of the ICP until May, 2011</p> <p>b. this staff member was unaware of the policy related to physician contact post procedure for information related to any complications or infections</p> <p>c. at this time, the procedure known by this staff member, in obtaining information related to possible post procedure infections is to instruct patients, as a part of their discharge instructions, to call the facility if they develop a fever</p> <p>4. interview with staff member NE at 3:40 PM on 11/2/11 indicated:</p> <p>a. after checking with the scheduler, it was found that the policy/procedure for sending a letter to the physicians, related to post procedure complications and infections, is not occurring</p>		<p>Governing Board meeting 12/27/11. 3c Physician responsible for reporting all infection/complication occurrences backe to MCEC. Patient given a list of "warning signs" to contact physician relate to possible post op infection or complication. 4a The Infection /Complication Reiport Policy has been modified ot reflect that the scheduler is not sending a letter, but that the MCEC Patient Care Coordinator is initiating this document. Update again clinical staff meeting on 1/5/12</p>		

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S0442	<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 policy and procedure review, employee health file review and staff interview, the infection control committee and infection control practitioner failed to ensure a safe, effective infection control plan related to communicable disease history was determined for 4 of 6 staff members (P1, P3, P4 and P5).</p> <p>Findings: 1. at 9:30 AM on 11/2/11, review of the policy "General Infection Control Practices for MCEC" (Medical Consultants Endoscopy Center), indicated: a. under "Policy", in item "1. Personnel", it reads: "...All personnel must comply with all Employee Health</p>	S0442	<p>1a. General Infection Control Practices for MEEC under "Policy" item 1. Personnel: The following changes were made to this policy. All personnel must comply with all medical consultants endoscopy center health requirement related to immunizations, serologic testing and PPD mantoux skin testing, yearly TB testing will be required and provided by medical consultants. Respirator fit testing is not applicable to nsg. care at MCEC and was deleted from this policy. 2. Staff members self report history of varicella will have all MCEC employees who are providing direct patient care will have serology testing completed. by 12/22/11. This will be done to confirm immunity and staff</p>	12/02/2011			

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	<p>Services health requirements related to immunizations, serologic testing, PPD (purified protein derivative) Mantoux Skin Testing (at BMH) [Ball Memorial Hospital] and respirator fit testing..."</p> <p>2. at 11:05 AM and 2:00 PM on 11/2/11, review of employee health file reviews for staff members P1, P3, P4 and P5 indicated all had self reported a history of Varicella</p> <p>3. at 1:00 PM on 11/2/11, interview with staff member ND, the infection control practitioner, indicated:</p> <p>a. the policy listed in 1. above does not specifically address what communicable diseases new employees will be required to report a history of</p> <p>b. the policy listed in 1. above is not specific as to how the communicable diseases should be reported for history, such as: a positive titer, documentation of immunization, etc.</p> <p>c. it was unknown by this staff member what the CDC (centers for disease control/prevention) recommended for communicable disease history in health care workers</p> <p>d. the infection control plan and policies are incomplete in relation to communicable disease standards for employees</p>		<p>without immunity will be revaccinated per guidelines CDC, State and Federal regulations. Self reporting no longer validated documentation. These changes are supported in our Policy and Procedure Employee/Physician Statement of Health. 3a. Our policy "General Infection Control Practices for MCEC will be ammended to address what new employee will be required to report a history of relation to communicable diseases. Information was obtained from the CDC on Nationally Notifiable Infection condition. This extensive list of health conditions will be reviewed by ea. MCEC employee with yes or no response and ea. yes addressed by the Administrator with confidentiality. 3b. Stated above employee will self report on CDC National Notifiable Infectious Condition is now in our Infection Control book to reflect requirement. 3d. Infection Control Policy and Procedure are in the process of becoming more detailed and complete related to communicable disease standard. Reviewed with staff individually outcome and updated policy 12/15 completed and ongoing monitoring Infection Control Nurse of immunization records with admininstrator responsibility support process allotted 4hrs weekly infection control duties. Reporting of process to governing board details quarterly.</p>				

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S0508	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2(c)</p> <p>(c) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the patient care staff.</p> <p>Based on document request, observation and interview, the facility lacked a list indicating laboratory tests performed at the center and laboratory services provided by a certified laboratory.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 10-31-11 at 0930 hours, staff #A1 was requested to provide a list of Point of Care (POC) tests and laboratory services provided by a certified laboratory and none was provided prior to exit. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the center lacked a list of POC tests and laboratory services provided by a certified laboratory. 	S0508	<p>Laboratory tests performed at the center needs listed and laboratory services provided by a certified laboratory. Updated written policy and procedure to list the correct POC test provided by the staff: INR, Glucometer and the HPone (Helicobactor) all Clia wavier. Labcorp certified lab does only Helicobactor with the histology specimen updated policy and procedure include Helicobactor as documented in Q0201. Staff inserviced 11/17/11 Policy and procedure was updated by the POC nurse and the infection control nurse enforced by the adminstrator. Reviewed with the medical staff and approved update by the governing board 12/27/11</p>	11/17/2011			

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S0606	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(b)(1)</p> <p>(b) The organization of the medical record service must be appropriate to the scope and complexity of the services provided as follows:</p> <p>(1) The services must be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time and/or part-time RRA or ART is not employed, then a consultant RRA or ART must be provided to assist the qualified person in charge. Documentation of the findings and recommendations of the consultant must be maintained.</p> <p>Based on document review and interview, the facility failed to utilize a qualified medical records (MR) director or consultant for their MR department. Findings:</p> <p>1. On 10-31-11 at 0930 hours, staff #A1 was requested to provide documentation including a personnel file for an RHIA or RHIT qualified medical records director or an RHIA/RHIT qualified medical records consultant and no documentation was provided prior to exit.</p> <p>2. On 11-02-11 at 1210 hours, staff #A4</p>	S0606	Employment outside RHIT consultants for medical record review for the center arrangement 11/17/11 for 2012. Hired date contracted 12/02/11. Listed in the contract services and included updated QA process and reporting structure medical staff and governing board.	11/17/2011			

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	confirmed that the center did not directly employ or contract with an RHIA or RHIT qualified individual for the medical record services at the center.				

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S0622	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(6)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(6) The center shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure, physician, and condition on discharge, in order to support continuous quality assessment and improvement activities.</p> <p>Based upon document review and interview, the center lacked an electronic medical records (MR) system for coding and indexing that allowed for retrieval of records by condition on discharge.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 11-02-11 at 0905 hours, review of patient log documents failed to indicate condition on discharge for the listed patients. On 11-02-11 at 1035 hours, staff #A1 was requested to provide a MR log indicating all patients transferred from the facility for 2010 and 2011 and none was provided prior to exit. On 11-02-11 at 1510 hours, staff #A4 confirmed that the electronic MR system 	S0622	<p>Lacked the electronic medical record retrieval of condition on discharge. IT nurse called G-Med provider of electronic records 11/11/11 and informed that no such report available with this program but new version available will meet this requiremnt. Reviewed at 12/27/11 governing board meeting and approved reviewing this vendor and other competitor communicating with RHIT.</p> <p>Retrieval of condition on discharge of each patient will be review of policy and procedure at the staff inservice on 12/01/11 and implemented with paper document indexing and will be monitored weekly by IT nurse until 100% compliance and enforced by administrator and medical director. Compliance will go to a quarterly random audit by external auditor with collaboration</p>	12/01/2011			

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	could not provide a list of transfer patients by system query.		RHIT correlate electronic record with the paper document. Documented electronic record patient transfer but not able to query but paper documentation log at this time with medical record number correlates to patient electronic chart. Again reviewing other vendors for a system that codes and indexes an administrative log on patient name, gastroenterologist, issue of concern, procedure, diagnosis, patient condition on discharge, and transfers, etc.		

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S0630	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(d)</p> <p>(d) The medical record must contain sufficient information to:</p> <p>(1) identify the patient; (2) support the diagnosis; (3) justify the treatment; and (4) document accurately the course of the patient's stay in the center and the results.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure the accuracy of medical records for 3 of 13 patients (N1, N5 and N9).</p> <p>Findings: 1. Review of patient medical records through out the survey process of 10/31/11 to 11/2/11, indicated: a. pt. record N1: A. listed "indications" for the colonoscopy was "screening colorectal cancer" B. listed on the patient consent form that the "Colonoscopy...indication" was "screening" C. had documentation in the physician's "Colonoscopy Report" that the indications were "Rectal Bleed" b. pt. N5 had one physician name circled, on the consent form, but the consent was signed by, and the procedure</p>	S0630	<p>1a.ABC,b Staff failure to ensure accuracy of medical records reviewed rules and regulation of record accuracy at clinical and medical staff inservice on 12/1/11 how to fill out the consent form re-checking all appropriate boxes with communication among caregivers if indication the same or if a change note comments to support the discrepancy, physician reinforced need to include referring diagnosis on indication along with other patient complaints to support documentation. Staff re-check correct phyician is listed on consent form. 1.c A-B Have removed defaults in discharge dispostion in G-Med so staff has to populate this field on discharge to prevent inaccurate discharge to home that was inaccurrate. Reviewed the updated policy and procedure for electronic medical records composition at the 12/1/11 inservice clinical and medical along with consent form</p>	12/01/2011			

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	<p>was performed by, a different physician</p> <p>c. pt. N9:</p> <p>A. had documentation by nursing staff at 10:17 AM on 1/14/11 that read: "Procedure was not done...will be going to ER..." (emergency room)</p> <p>B. had documentation in the "Discharge" section of the chart that read: "Discharging to home"... "yes"</p> <p>2. interview with staff member NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. there is a discrepancy in the medical record for pt. N1 in regards to whether the colonoscopy was a screening or for rectal bleeding</p> <p>b. the incorrect physician name was circled on the consent form for pt. N5 by staff completing the form, creating an inaccurate document</p> <p>c. the nursing staff must over ride the "default" documentation in the "Discharge" section when the patient isn't discharged to home, that was not done for patient N9</p> <p>3. a policy/procedure related to accuracy of the medical record was requested during the survey and none was provided prior to exit</p>		<p>random audit internal and external quarterly enforced by the administrator and medical director. Reviewed and approved by governing board 12/27/11.</p>				

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure the completeness of records for 5 of 13 patient medical records reviewed (pts. N1, N2, N3, N4 and N8) and lacked a policy/procedure to ensure all entries in the medical record (MR) were legible.</p> <p>Findings:</p> <p>1. review of patient medical records through out the survey process of 10/31/11 to 11/2/11 indicated:</p> <p>a. pts. N1, N2, N3 and N8 lacked indication on the "Informed Consent for Gastrointestinal Endoscopy" form (lower section of the page) that the physician "Reviewed/assessed history & physical note prior to procedure" (physician failed to check the box preceding this statement)</p> <p>b. without a time of authentication of the "Informed Consent for Gastrointestinal Endoscopy" form by practitioners, it cannot be determined that the authentication was prior to the procedure start time</p> <p>c. pt. N4 lacked completion on the</p>	S0640	<p>Corrected the deficiency on 12/1/11 a.and b removed box on consent that stated reviewed and assessed history and physical prior to procedure and now done electronically in the prep area by the physician. Patient is not taken to the procedure room until the physician has reviewed, assessed and documented electronically with time to authenticates this process prior to procedure start. Staff accesses electronic record to review physician documented electronically this process to prevent in the future and administrator and medical director inforces this process. 1c. Review with clinical staff and medical staff on accuracy of completeness of documented informed consent on "Patient Rights" etc. if left blank not done at staff meeting 12/01/11 with review of state and federal regulation guidelines and policy and procedure. 3. Revised policy and procedure for medical record composition and completeness with random internal and quarterly external audit of medical records. 4. Revised policy for medical</p>	12/01/2011			

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	<p>"Informed Consent for Gastrointestinal Endoscopy" form of indication that the patient received: "Patient Rights", "Advance Directives" information, "Disclosure of Financial Interest...", "Moderate Sedation" information, whether the patient to have an upper GI (gastrointestinal) procedure, a lower GI procedure, a possible biopsy and which provider was to be performing the procedure (all boxes preceding these items were left blank)</p> <p>2. at 2:30 PM on 11/1/11, interview with staff member NB indicated the charts as listed in 1. above were lacking completeness as noted</p> <p>3. a policy/procedure related to completeness of the medical record was requested during the survey and none was provided prior to exit</p> <p>4. The policy/procedure Medical Record Entries (reviewed 07-20-11) and Medical Record Completion (reviewed 07-20-11) failed to indicate a process for verifying information with questionable legibility in the MR.</p> <p>5. On 11-02-11 at 1730 hours, staff #A1 confirmed the center lacked a policy/procedure for verifying illegible</p>		records entries #1a. with G-Med. Deficiency was reviewed and approved by the governing body 12/27/11.				

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	information in the patient record.				

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S0644	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(2)</p> <p>All entries in the medical record must be as follows:</p> <p>(2) Made only by authorized individuals as specified in center and medical staff policies.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure that entries made in the patient medical records were those by authorized individuals, or those employees of the facility, in 7 of 13 records reviewed (pts. N2, N6, N8, N9, N10, N12 and N13).</p> <p>Findings:</p> <p>1. at 11:30 AM on 11/1/11, review of the policy "Identification of Authors and Authentication of Medical Record Entries", indicated:</p> <p>a. under "Purpose", it reads: "To provide a method for verifying and identifying the authentication of all entries in the medical record."</p> <p>b. under "Policy", it reads: "...A method is established for identification of the author of the entry..."</p> <p>c. under "Procedure", it reads: "1. Identification of authors A. Physicians and other licensed health care professional complete a signature form..."</p>	S0644	<p>LPN noted is now contracted employee with job description and orientation documented including signature form addressing the center confidentiality and security of electronic medical record with authorization entries made in the patient medical records. Policy and procedure on medical record entries was updated.</p> <p>Adminstrator responsible security of medical records. Auditing and review process will be detailed task outside contracted RHIT</p>	12/02/2011			

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	<p>2. review of patient medical records N2, N6, N8, N9, N10, N12 and N13 through out the survey process of 10/31/11 to 11/2/11, indicated a LPN (licensed professional nurse) in the physicians' offices had documented in the "preop" section of the patients' history and physical data</p> <p>3. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the LPN who entered information into the electronic medical record, works in the physicians' offices and is not an employee of the surgery center (electronic record flows back and forth between both entities)</p> <p>b. the LPN from the physician office has not completed a signature form at the surgery center</p> <p>c. the policy, as stated in 1. above, does not address the specific "licensed health care professional" that are allowed to make entries in the surgery center medical record</p> <p>d. the policy, as stated in 1. above, does not address how the medical record may be accessed and documented in, by office staff (or other staff not employed by the surgery center)</p>			

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S0658	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(f)(6)</p> <p>All patient records must document and contain, at a minimum, the following:</p> <p>(6) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to clearly indicate the surgical consents were witnessed the day the patient signed the consents, for 12 of 12 patients with surgical procedures performed (N1 through N8 and N10 through N13).</p> <p>Findings: 1. review of the policy and procedure "Consent, Informed", at 11:30 AM on 11/1/11, indicated: a. under "Policy", it reads: "All endoscopy procedures must have a properly completed informed consent in advance of the date of the procedure..." b. under "Procedure", in item #4., it reads: "The consent must be signed, dated, and witnessed in advance of the date of the procedure..."</p>	S0658	<p>Surgical consent failed to clearly indicate witnessed the day patient signed. 1 and 2 Policy for "Patient Admissions" has updated and revised. 3. A date has been added to the witness's signature on the informed consent to eliminate confusion and 4. " Patient Admission " policy has been revised to be in compliance with the "Informed Consent " policy. Staff update on new printed consent forms 12/01/11 Forms implemented by administrator and medical director with approval at the governing board 12/27/11</p>	12/01/2011

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	<p>2. review of the policy and procedure "Patient Admission", at 11:40 AM on 11/1/11, indicated:</p> <p>a. under "Policy", in item 2., it reads: "The patient will be given time to read consent,...After all questions have been answered, the patient will sign the forms with the RN (registered nurse) witnessing the signature..."</p> <p>3. review of patient medical records N1 through N8 and N10 through N13 during the survey process of 10/31/11 to 11/2/11, indicated:</p> <p>a. the patients signed their procedure consent forms days prior to the procedure date</p> <p>b. physicians signed the consent forms on the day the procedures were performed</p> <p>c. the witness to the patients' signed consents is not dated and it cannot be determined that there was a witness to the patients' signatures</p> <p>4. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the procedure consents are signed in the physician offices, prior to the day of the endoscopy procedure, when pre procedure testing is done</p> <p>b. it cannot be determined, since the witness signatures are not dated, that witnessing is done the day the patient</p>			

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	<p>signs the consent forms</p> <p>c. the policy listed in 2. above (Patient Admission), is not a valid policy as the RN, at the time of admission to the surgery center, does not present the consent to the patient and procure a signature (this is done as stated in 4. a., at the physician's office on a day prior to the day of the procedure)</p> <p>d. there is a discrepancy in facility policies</p>			

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S0676	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(g)</p> <p>(g) All original medical records or legally reproduced medical records must be maintained by the center for a period of seven (7) years in accordance with subsection (c)(6) and (c)(7), must be readily accessible, in accordance with the center policy and must be kept in a fire resistive structure.</p> <p>Based on document review and interview, the center lacked a departmental waiver for off-site storage of medical records (MR).</p> <p>Findings:</p> <p>1. The policy/procedure Medical Record Storage (reviewed 07-20-11) and Medical Record Retention, Retirement and Destruction (reviewed 07-20-11) lacked a provision for off-site storage including an approved waiver from the Indiana State Department of Health.</p> <p>2. During an interview on 11-01-11 at 1210 hours, staff #A1 confirmed that MR were being stored in a location away from the center and no approved waiver had been obtained from the department.</p>	S0676	<p>Medical record retention , and retirement policy and procedure updated and the medical record retained in the center. Not requesting a departmental waiver for off site storage of medical records. Responsibility of administrator and medical director retain in unit remaining paper chart. Input of RHIT of medical record process update current regulations ongoing.</p>	12/02/2011			

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S0780	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure that 1 of 1 transfer patients had an order for transfer to an acute care facility (pt. N9) and lacked a uniform policy/procedure for authenticating verbal orders in the medical record (MR).</p> <p>Findings:</p> <p>1. at 9:30 AM on 11/1/11, review of the transfer record of pt. N9 indicated there was no physician order to transfer the patient</p> <p>2. at 2:30 PM on 11/1/11, interview with staff member NB indicated the nursing</p>	S0780	<p>Ensure each patient has a discharge order signed by the physician who performed the transfer lacking this order. Revised policy identification of author and authentication of medical record entries to say 5 days instead of 30 days and uniform interval for authenticating entries in the electronic medical records. Stated in post-op nursing notes physican instructed patient to go to the ER as a verbal order but not authenticated by physician. Reviewed and inservice clinical and medical staff actual physician signautre of discharge order with in 30 minutes. All transfer incident reporting for Q/A safety officer, administrator and medical director monitoring at time of incident randomly quarterly and</p>	12/01/2011	

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	<p>staff failed to obtain, or document, a physician order to transfer pt. N9 to the acute care hospital</p> <p>3. The policy/procedure Verbal Orders (reviewed 07-20-11) indicated the following: " The verbal order must be signed by the physician within five working days. " The policy/procedure lacked the requirement to date the entry when authenticated by the physician.</p> <p>4. The policy/procedure Identification of Authors and Authentication of Medical Record Entries (reviewed 07-20-11) indicated the following: " Each verbal order is also dated and authenticated within thirty days by the person who gave it.</p> <p>5. During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedures lacked a uniform interval for authenticating entries in the MR.</p>		<p>enforcement. Reviewed and approved by governing board. 12/27/11.</p>		

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S0830	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(c)(1)(F)(i)</p> <p>The medical staff shall write and implement policies and procedures and the governing body shall approve policies and procedures which include but are not limited to, the following:</p> <p>(F) The delineation of preanesthesia, intra-operative, and post-anesthesia responsibilities as follows:</p> <p>(i) The completion, within forty-eight (48) hours before surgery, of a preanesthesia evaluation for each patient by an individual qualified to administer anesthesia for all types of anesthetics other than local and updated according to center policy (when more than forty-eight (48) hours) before surgery.</p> <p>Based on patient medical record review and staff interview, the facility failed to ensure that documentation was clear that the pre anesthesia evaluation was performed prior to the surgical procedure for 12 of 12 patients with procedures performed (N1 through N8 and N10 through N13).</p> <p>Findings: 1. review of patient medical records for patients N1 through N8 and N10 through N13 through out the survey process of 10/31/11 to 11/2/11, indicated:</p>	S0830	<p>Clear documentation pre anes evaluation prior to procedure captures the time in the electronic system. Noted but the current captures as part of the procedure report. Updated policy state the physician will perform the pt. pre-anes evaluation and history and physical at the same time and implement signature of the orders. Occur in the prep area prior capturing date, time and signature. IT nurse randomly audit weekly and compliance quarterly basis. Review again with staff on the inservice 12/01/11. Responsible administrator and medical</p>	11/11/2011			

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	<p>a. the electronic document containing the pre anesthesia evaluation, performed by the practitioner, is embedded within the operative report</p> <p>b. the electronic signature by the practitioner is timed after the procedure has ended and the patients have been discharged from the procedure room to the recovery area</p> <p>2. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the current computer system does not capture the time of the practitioner's pre anesthesia evaluation and selection of an ASA (American Society of Anesthesiologists) level prior to the operative procedure, as is required</p> <p>b. currently, the patient medical records for patients N1 through N8 and N10 through N13 have electronic documentation of a pre anesthesia evaluation by physicians that is timed after the procedures have been completed</p>		director and support IT nurse monitoring of process.	

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S0860	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(B)</p> <p>Requirements 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>(B) A requirement that an appropriate history and physical workup must be in the chart of every patient before surgery. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting practitioner which includes, but is not limited to, vital signs, allergies, any significant risk factors, and date written.</p> <p>Based on policy and procedure review, patient medical record review and staff interview, the facility failed to ensure that documentation was clear that a history and physical evaluation was performed prior to the surgical procedure for 12 of 12 patients with procedures performed (N1 through N8 and N10 through N13).</p> <p>Findings: 1. review of the policy and procedure "History and Physical of Patient" at 11:30</p>	S0860	<p>Failure to ensure clearly history and physical evaluation performed prior to procedure per policy and procedure with the electronic document embedded within the operative report with electronic signaute timed after the procedure ended. The physician is now documenting physical and history exam prior to the start of the procedure with a date and time performed in the prep area. Staff inservice 12/1/11 on the process and ongoing audit the first week with 100% compliance</p>	12/01/2011			

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	<p>AM on 11/1/11 indicated:</p> <p>a. under "Policy", it reads: "All patients seen at Medical Consultants Endoscopy Center will have a completed history and physical on the chart before the procedure begins..."</p> <p>2. review of patient medical records for patients N1 through N8 and N10 through N13 through out the survey process of 10/31/11 to 11/2/11, indicated:</p> <p>a. the electronic document containing the medical history and physical, performed by the practitioner, is embedded within the operative report</p> <p>b. the electronic signature by the practitioner is timed after the procedure has ended and the patients have been discharged from the procedure room to the recovery area</p> <p>3. interview with staff members NA and NB at 2:30 PM on 11/1/11 indicated:</p> <p>a. the current computer system does not capture the practitioner's review, electronically, of the patient's history and physical prior to the operative procedure as is required</p> <p>b. currently, the patient medical records for patients N1 through N8 and N10 through N13 have electronic authentication by physicians that is timed after the procedures have been completed</p>		<p>now random audit monthly than quarterly by IT nurse with support administrator and medical director. Review and approval at the 12/27/11 governing board meeting.</p>				

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S0862	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(d)(2)(C)</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>(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:</p> <p>(i) Emergency call system. (ii) Oxygen. (iii) Resuscitation equipment. (iv) Defibrillator. (v) Cardiac monitors. (vi) Tracheostomy set. (vii) Oximeter. (viii) Suction equipment. (ix) Other supplies and equipment specified by the medical staff.</p> <p>Based on document review and interview, the facility failed to have required emergency equipment available for use for 2 of 9 required emergency equipment. Findings: 1) The policy/procedure Crash Cart Inventory (reviewed 07-20-11) failed to indicate a tracheostomy set or oximeter was listed as available for use on the code</p>	S0862	Tracheostomy set was available on the Emergency Cart but not noted in the policy and procedure which was updated and the availability of the oximeter for the Emergency cart. Reviewed and updated the policy and procedure on annual cardiac and nurse call drill to indicate the oximeter availability in a code with use of the emergency cart. Inservice the staff on 11/17/11 with competent cardiac nurse input supported by	11/17/2011	

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	<p>cart.</p> <p>2. The policy/procedure Checking the Emergency Cart and Annual Cardiac and Nurse Call Drills (reviewed 07-20-11) failed to indicate an oximeter was available.</p> <p>3) During an interview on 11-02-11 at 1730 hours, staff #A1 confirmed that the policy/procedures lacked the required equipment.</p>		<p>the administrator and medical director. Objectively review policy and procedure with real time walk through so documentation support process.</p>		

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S0906	<p>410 IAC 15-2.5-5 PATIENT CARE SERVICES 410 IAC 15-2.5-5(a)(2)</p> <p>(a) Patient care services must require the following:</p> <p>(2) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.</p> <p>Based on employee file review and staff interview, the facility failed to implement the job description requirements for 1 of 1 instrument tech files reviewed, in ensuring certification in resuscitation competency (P4).</p> <p>Findings: 1. at 11:05 AM on 11/2/11, review of personnel files indicated: a. staff member P4 was an instrument technician hired 10/20/03 b. the job description in the P4 personnel file was titled "Endoscopy Technician" c. the "Endoscopy Technician" job description listed under "Qualifications": "A. High School Graduate, BCLS (basic cardiac life support), if not BCLS willing to take training within the first six months..." d. the CPR (cardiopulmonary resuscitation) card in the personnel file of staff member P4 had a 10/31/11 expiration date</p>	S0906	<p>Endoscopy technician schedule for CPR recertification. Outdated Oct. 31 2011 excluded assisting in room until CPR update, staffing only in the decontamination with scope cleaning. Administrator evaluation of staff meeting job requirements deficiency. Endoscopy technician completed.</p>	12/01/2011

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	<p>2. interview with staff member ND at 1:10 PM on 11/2/11 indicated:</p> <p>a. the facility staff all renewed their CPR/BCLS in October, but staff member P4 was absent that day</p> <p>b. CPR is required, per the job description, for staff member P4</p> <p>c. staff member P4 has let their CPR expire and was still currently working within the facility</p>						

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S1042	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(4)</p> <p>Pharmaceutical service must have the following:</p> <p>(4) A formulary.</p> <p>Based on document review and interview, the center failed to follow its policy/procedure for maintaining a medical staff-approved formulary for its pharmacy services.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Pharmacy Committee (reviewed 07-20-11) indicated the following: "The pharmacy committee ... will consist of the Director of Nursing ... the Medical Director and the pharmacy consultant ...The pharmacy committee will have the following responsibilities: ... [including] development and periodic updating of a formulary ... subject to approval ... [by the medical staff]." The center document Formulary lacked an indication when it was last updated/approved by the medical staff. During an interview on 11-01-11 at 1210 hours, staff #A1 confirmed that no documentation of formulary approval by the medical staff was available. 	S1042	<p>Policy and procedure update of the approved formulary with signature and date approval pharmacist 12/02/11, administrator, medical director and the governing board CEO consist of the pharmacy committee with documentation supporting the process. Reviewed and approved by the medical staff 12/09/11 and reviewed and approved 12/27/11 governing board . Implemented by the administrator organizing the meeting. Ongoing frequency of monitoring due to the drug shortages.</p>	12/02/2011

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S1146	<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 safely maintain refrigerated medications and laboratory test chemicals for patients at the center.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Refrigerators (reviewed 10-31-11) indicated the following: " Thermometer is kept in refrigerator, and refrigerator is maintained at 37 to <u>42</u> F (2 - <u>8</u> C). " The policy/procedure Medication Storage (reviewed 10-07-11) indicated the following: " Refrigerate - temperature that is thermostatically maintained between <u>-2</u> C (<u>36</u> F) and 8 C (46 F). " During a facility tour on 11-02-11 at 0920 hours, the following condition was 	S1146	<p>Failure to safely maintain refrigerated medications and laboratory test in the center resulted in automatic destruction of the HPone, insulin and cardizem maintained in the refrigerator. Purchased new medical grade refrigerator withGurardian Alarm Thermometer and updated policy and procedure with updated log sheet. Inservice with staff on the new log sheet, ISDH recommeded ranges, list on outside refrigerator of listed drugs and accepted ranges. Discussed F versus C misunderstanding of staff knowledge of the log sheet discrepancies. Policy and procedure was reviewed by pharmacist auditor and approved by the medical and governing board. Review again at the 1/5/12 inservice due to multiple on vacation. Random auditing by the infection control nurse at first</p>	12/02/2011			

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	<p>observed: The Document/exhibit Refrigerator/Freezer Location: Med Room for the month of October 2011 indicated the following: Refrigerator <u>46</u> F (8 C) or below. From 10-03 until 10-21, recorded temperatures were 0 degrees. Contents of the refrigerator included one thermometer with a range from - 5 C to 15 degrees C, 4 boxes of HPone Helicobacter Pylori testing controls lot 080211 exp 02-2013 with the following statement on the packaging: store between 2 and 8 degrees C. The refrigerator also contained one box of Humulin Insulin lot A 7503236 exp 4-2013.</p> <p>4. During an interview on 11-02-11 at 1035 hours, staff #A1 indicated that the refrigerator temperatures indicated on the policy/procedures were not accurate and the contents in the med room refrigerator would be discarded immediately.</p>		weekly if 100% compliance than quarterly.		

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S1154	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(C)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.</p> <p>Based on document review, the center failed to perform a triennial analysis on its operational and maintenance records for all mechanical equipment at the facility.</p> <p>Findings:</p> <p>1) The policy/procedure Maintenance, Physical Environment and Safety (reviewed 07-20-11) lacked the provision for a triennial analysis of operational and maintenance records.</p> <p>2) On 11-01-11 at 1235 hours, staff #A1 confirmed that the center was not performing a triennial analysis of its</p>	S1154	<p>Trimedix annual PM 12/09/11 on mechanical equipment I reviewed and requested the triennial analysis of operational and maintenance equipment. Pending the result of the documentation. Expect final documented information by 1/13/12 Responsibility of administrator of implementation with support of the Safety nurse in my absence. Report reviewed and approval at the governing board 12/27/11 Update to staff on 1/5/12 of the purpose of the process.</p>	11/11/2011

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	operational and maintenance control records.				

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S1164	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(i)</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>(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on policy and procedure review, observation, and interview, the facility failed to implement its policy related to the removal of faulty equipment in one area toured.</p> <p>Findings: 1. at 11:30 AM on 11/1/11, review of the policy and procedure "Equipment Maintenance and Electrical Safety", indicated: a. under "Procedure", in item 3., it reads: "Any equipment that malfunctions or appears to malfunction will be taken</p>	S1164	<p>Failure remove malfunction equipment removed and discarded appropriately and reviewed updated policy and procedure with clinical staff and medical staff. Trimedix QA process of equipment on November visit ongoing annual monitoring responsible of administrator, and endoscopy tech.</p>	11/14/2011			

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	<p>out of service and reported to the DON (director of nursing). The piece of equipment will be tagged "Broken, Do not use" and will be taken out of service until repaired."</p> <p>2. while on tour of the supply/storage room at 4:25 PM on 10/31/11, it was noted on a counter top that one piece of equipment, a Fujinon endoscopy device with an equipment asset number of 117681, had a preventive maintenance date of 11/09 (and a due date for preventive maintenance of 11/10)</p> <p>3. interview with staff member NA at 4:40 PM on 10/31/11, indicated that:</p> <p>a. the Fujinon equipment was malfunctioning and needed to be removed from the facility</p> <p>b. the policy, listed in 1. above, was not followed as the Fujinon was not tagged as "Broken, Do not use"</p>			

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S1166	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(ii)</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>(ii) There must be evidence of preventive maintenance on all patient care equipment.</p> <p>Based on document review and interview, the center failed to document preventive maintenance (PM) on patient care equipment for its call light/code system and annual PM for the emergency generator. Findings: 1. On 11-01-11 at 1630 hours, staff #A1 was requested to provide supporting documentation of PM for the TekTone nurse call system and annual emergency generator PM and none was provided prior to exit. 2. During an interview on 11-02-11 at</p>	S1166	<p>Trimedex annual PM for call light/code sytem 2011 and provided copy of 2010 PM. Dickerson provided annual PM for emergency generator for 2010 and 2011 on site and reviewed loaded and unloaded testing with housekeeper 11/17/11. Updated organization of contract manual. Responsibility of administrator to organize manual and implementing grid recommendation by surveryor for overall assessment of PM process. Assigning Safety nurse task to facilitate workload.</p>	12/02/2011			

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	1730 hours, staff #A1 confirmed that no documentation of PM for the TekTone nurse call system or emergency generator was available.				

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S1168	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iii)</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>(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.</p> <p>Based on document review and interview, the center lacked documentation of electrical current leakage testing or triennial analysis of preventive maintenance (PM) records on all patient care equipment in use at the center.</p> <p>Findings:</p> <p>1. PM records lacked evidence of electrical current leakage testing and triennial analysis by either the center or</p>	S1168	<p>Trimedix annual pm 12/09/11 on mechanical equipment I reviewed and requested the triennial analysis of operational and maintenance equipment and leakage testing 11/11/11. Pending the result of the documentation..Expect documented information by 1/13/12. Updated policy and procedure. Responsibility of administrator of implementation with support of the safety nurse in my absence. Report on reviewed and approval at the governing board 12/27/11. Update to staff on 1/5/12 of the purpose of the process.</p>	12/02/2011	

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	<p>the biomedical engineering services provider for patient care equipment.</p> <p>2. During an interview on 11-01-11 at 1240 hours, staff #A1 confirmed that PM records lacked documentation of electrical current leakage testing and that triennial analysis of the patient care equipment PM was not being performed.</p>						

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S1170	<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 and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Checking the Emergency Cart and Annual Cardiac and Nurse Call Drills (reviewed 07-20-11) lacked a description of the process for checking the defibrillator according to the manufacturer ' s recommendations. The center document Code Cart 	S1170	1a and b Updated the policy and procedure to reflect the recommended manufacturer inspection and testing of the deibrillator listing the visual inspection checklist of all devices for defects and check list all necessary supplies. Inservice clinical and medical staff 12/1/11. Safety nurse review checklist is complete on random basis (monthly) The policy update responsibility of the administrator and review with approval safety issue at the governing board 12/27/11.	11/17/2011			

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	<p>Checklist Endoscopy Center dated September 2011 lacked a description of the process for checking the defibrillator according to the manufacturer ' s recommendations.</p> <p>3. The Physio-Control LifePak 9 service manual (1993 edition) indicated the following under the heading MAINTENANCE and TESTING SCHEDULE: " Testing should be preceded by a thorough visual inspection of the defibrillator/monitor/pacemaker. Examine the device and accessories for cracks in the case and cables, pitted paddle electrode surfaces, presence of gel on paddles or paddle storage area, and for proper function of controls. If damage is suspected, corrective action should be taken immediately Check that all necessary supplies and accessories are present (e.g., gel, ECG paper, ECG and pacing cable, electrodes, etc.) "</p> <p>4. During an interview on 11-01-11 at 1610 hours, staff #A1 confirmed that the policy/procedure and center checklist lacked a checklist or reference guide based on the manufacturer ' s recommendations.</p>			

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S1198	<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 lacked documentation of participation with community, state and federal emergency and disaster preparedness agencies.</p> <p>Findings:</p> <p>1) On 10-31-11 at 0930 hours, staff #A1 was requested to provide a disaster policy/procedure and documentation of regular participation in local, state, and/or federal emergency and disaster preparedness exercises and none was provided prior to exit.</p> <p>2) During an interview on 11-01-11 at 1430 hours, staff #A1 indicated that the center had no contact or coordination with any local, regional, state or federal emergency services agency to participate in a training exercise or related activity since the final months of 2009.</p>	S1198	<p>Ongoing process with initial verbal and written contact with local community request to assist in emergency and disaster preparedness agencies with request for participation MCEC in training activity or exercise. Documented with a telephone call followed by a letter of interest to participate to Jason Rogers Emergency Management Director. Responsibility of administrator reporting to the governing board community participation in local disaster emergency preparedness. Ongoing process in implementation.</p>	12/02/2011			

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