

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001147	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 02/01/2012
NAME OF PROVIDER OR SUPPLIER INVERNESS SURGERY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 8004 CARNEGIE BOULEVARD FORT WAYNE, IN 46804		
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Q0000	<p>The visit was for a re-certification survey.</p> <p>Facility Number: 004581</p> <p>Survey Date: 1-30-12 to 2-01-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 03/08/12</p> <p>4/19/12 revised due to IDR</p>	O0000	Agreed		

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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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 policy and procedure review, medical staff rules and regulations review, patient medical record review and staff interview, the facility failed to ensure records were legible in 9 of 16 charts (N2, N4, N5, N7, N8, N11, N12, N13 and N14) and failed to ensure a complete medical record for 12 of 16 charts (N2, N3, N4, N5, N6, N7, N11, N12, N13, N14, N15 and N16).</p> <p>Findings: 1. at 2:35 PM on 2/1/12, review of the policy and procedure "Guidelines for Maintaining the Medical Record as a Medical-legal Document", indicated:</p>	Q0162	Q 162 – 416.47(b) Form and Content of Record Plan of Correction The facility policies MR 01 – Documentation: Carting and Charts, MR 02 Guidelines for Maintaining the Medical Record, and ADM 06 – Confidentiality of the Medical Record were rewritten and a new policy created MR 09 – Completeness and Legibility of the Medical Record by the Director on 02/17/12 to specify that all chart forms, including consents, pre-op, post-op, intra-op, and anesthesia records must be completed, with all indicated spaces filled in, with concise and legible documentation by the physician and nursing. The	02/28/2012			

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	<p>a. under "Procedure", it reads: "...G. All blanks should be completed on special forms: special reference is made to consent forms."</p> <p>2. review of the Medical Staff Rules and Regulations, approved by the medical staff 9/28/09 and by the governing board on 10/24/09, indicated:</p> <p>a. in item "VIII.", it reads: "The attending physician shall be responsible for the preparation of a complete and legible medical record for each patient he/she admits..."</p> <p>3. review of patient medical records through out the survey process of 1/30/12 to 2/1/12, indicated:</p> <p>a. pt. N2:</p> <p>A. lacked completion on the "Anesthesia Record" form in the "Anesth Hx:", and "Medications:" area in the "Preoperative Evaluation" section of the form, and lacked documentation of "Reassessment in OR prior to induction with: Status Changed/Unchanged" not noted by the anesthesiologist</p> <p>B. had illegibility in the lower section of the " Recovery Room Record " form in the section "Patient Assessment Parameters" (in section 11. "Physician Visited")</p> <p>b. pt. N3 lacked completion by nursing staff of the times pre procedure</p>		<p>director and medical director presented the updates and new policy to the Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board approved the revisions. The physician, and anesthesia staff were notified by the Medical Director that per the policies MR 01, MR 02, MR 09, and ADM 06, and the facility Medical Staff Rules, <u>each</u> physician is responsible for and must legibly complete all information and fill all blanks on facility medical records pertaining to their area of service, effective 03/01/12.</p> <p>The facility director re-educated the nursing staff regarding the necessity for completeness and legibility of charting in the medical record. Staff were reminded to chart concisely per the policy and to avoid "write-overs" in the medical record. Each staff member reviewed the new and revised policy and signed a roster confirming their understanding of the need for complete and legible documentation. The post-operative nursing staff (RN) and medical records clerk will monitor 100% of the medical records, and document exceptions to the policy on the green chart log included with each chart. The facility director posted signage in the patient care and employee areas of the facility, reminded physicians and staff to complete each medical record</p>				

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	<p>medications (Kefzol, Zantac, Reglan, and Versed) were given (on the "Pre-Op Record" form) and lacked documentation by the anesthesiologist on the "Anesthesia Record" form in the areas: "Anesthesia Plan Proposed: General/MAC (monitored anesthesia care)/Regional"; "Airway Class: 1, 2, 3, or 4"; "Time" of pre op medications given; and "Anesthesia Complications: Yes/No" (in the " Post Operative Evaluation " section)</p> <p>c. pt. N4:</p> <p>A. lacked notation on the "Anesthesia Record" form in the areas: "Gas Off:", Post Op "SPO2, HR, B/P, RR " ; and "Anesthesia Complications: Yes/No" (in the " Post Operative Evaluation " section)</p> <p>B. had illegibility on the "Recovery Room Record" form in three areas: Oxygen "Time On"; notes in the "1130, 1135 and 1145" areas (top of the page); and in the "Patient Assessment Parameters" section in the 8. "Nausea" and 9. " Pain Intensity... " areas</p> <p>d. pt. N5:</p> <p>A. lacked completion by the anesthesiologist on the " Anesthesia Record " form in the " Extubated: OR/PACU " area of the " Postoperative Anesthesia Note " section</p> <p>B. was illegible on the " Recovery Room Record " form in the " SAO2 " area at " 1340 " and " 1345 " ; the</p>		<p>legibly and in its entirety.</p> <p>Monitoring Compliance</p> <p>The director or designee will sample random medical records each month and conduct a review for chart completeness and legibility. Mary Kay Sterrett, the facility third-party medical records review consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records meeting.</p>				

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	<p>amount of " LR (Lactated Ringgers) " intravenous solution administered; and in the " Patient Assessment Parameters " section " 12. Significant Other Visited " area</p> <p>e. pt. N6 lacked completion by the anesthesiologist on the " Anesthesia Record " form in the " Gas On: " and " Gas Off " section; in the " Anesthesia End " time section; and in the " Extubated: OR/PACU " section of the " Post Operative Anesthesia Note " section</p> <p>f. pt. N7:</p> <p>A. lacked completion by admission and/or nursing staff on the " Authorization to Treat " form in the Advance Directive section where staff checked that the patient did have an Advance directive, but failed to note if the copy was " obtained " or " no copy provided "</p> <p>B. lacked completion on the " Anesthesia Record " form in the " Gas Off: " section and in failing to mark the box for " Monitors/Equipment--Pre-op Equip checked... "</p> <p>C. had illegibility in several areas of the " Recovery Room Record " form in the section just above " Patient Assessment Parameters "</p> <p>g. pt. N8 had a write over with the first time noted with vital signs at the top of the page</p> <p>h. pt. N11:</p>			

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	<p>A. lacked completion by the anesthesiologist of the pre op antibiotic and the time it was given and in the area of " Gas Off "</p> <p>B. had illegibility on the " Recovery Room Record " form with the next to last time of vital signs documented (write over), in writing KO (keep open) for the IV (intravenous) amount (write over), and on the " Pre-Op Record " form in the area " Any loose or capped teeth? " (write overs noted)</p> <p>i. pt. N12:</p> <p>A. lacked documentation by the anesthesiologist in the " Gas Off: " section and in the " Post Operative Anesthesia Note " section in the area: " Extubated: OR/PACU "</p> <p>B. was illegible with a write over in the 8th notation of vital signs on the " Recovery Room Record " form; with a write over of medication given pre operatively on the " Pre-Op Record " form; and in the time of physician authentication on the " Consent... " form</p> <p>j. pt. N13:</p> <p>A. anesthesia failed to complete the " Anesthesia Record " form in the areas of: " Antibiotic " given pre operatively; " Reassessment in OR Prior to Induction: Status Changed or Unchanged " ; and in the " Post Operative Anesthesia Note " section for " Extubated: OR/PACU "</p> <p>B. had illegibility in the " Patient</p>			

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	<p>Assessment Parameters " section of the " Recovery Room Record " form in several areas of write overs</p> <p>k. pt. N14:</p> <p>A. lacked documentation by anesthesia in the " Reassessment in OR Prior to Induction: Status Changed/Unchanged " on the " Anesthesia Record " form</p> <p>B. had write overs on pages 16 and 17 of the " 23 Hour Patient Assessment Record " form and write overs in the section of " Gas On: " and " Anesthesia Start " time on the " Anesthesia Record " form</p> <p>1. pts. N15 and N16 lacked documentation by anesthesia of the " Gas Off " time on the " Anesthesia Record " form</p> <p>4. interview with staff member NB at 3:30 PM on 2/1/12 indicated:</p> <p>a. documentation is lacking, mainly on the " Anesthesia Record " forms and illegibility is noted, mainly on the " Recovery Room Record " form for charts N1 through N16 as listed in 3. above</p> <p>b. there is no specific facility policy related to completeness of the medical record or legibility of the medical record</p>			

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Q0181	<p>416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice.</p> <p>Based on document review, policy and procedure review, and staff interview, the facility failed to ensure the safe storage of refrigerated medications by failing to implement the facility policy for pharmacy refrigerator temperatures.</p> <p>Findings:</p> <p>1. at 12:00 PM on 1/31/12, review of the policy and procedure "Medication Refrigerators", PC 093, indicated:</p> <p>a. under "Procedure", it reads: "...B. Refrigerators containing medication shall contain a thermometer and shall be kept between 36 degrees F and 46 Degrees F..."</p> <p>2. at 12:55 PM on 1/30/12, review of the "Pre-OP and PACU (post anesthesia care unit) Daily Checklist" in the company of staff member NC, indicated:</p> <p>a. in October 2011, 16 of 21 days the medication refrigerator was checked, were out of compliance with the 36 to 46 degree range required by facility policy (30 to 34 degrees)</p> <p>b. in November 2011, 1 day of patient care service lacked a pharmacy refrigerator temperature check and 12 of 19 days were below the recommended</p>	O0181	<p>Q181 – 416.48(a) Administration of Drugs</p> <p>The facility director revised the policy PC 093 – Medication Refrigerators on February 3, 2012 to include specific actions the employee must take upon discovering that a temperature reading is out of range, to correct the temperature, and the use of the correct chain of command to communicate this information as appropriate. When discovering an out of range reading, the policy change requires the staff member to seal the door firmly, check the temperature reading, temperature setting, and recheck the temperature in one-hour. If the temperature setting is incorrect, the employee is to fix the temperature, and document the action on the refrigerator log skeet. If the temperature remains out of range, the staff member must notify the director or designee. The director revised the medication refrigeration daily log to include the re-checking of an out-of-range temperature in one hour, and a space to document the notification of the director of designee when a temperature is confirmed to be out of range.</p> <p>The director purchased a new refrigerator for the pharmacy on</p>	02/27/2012			

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	<p>low of 36 degrees (32 to 34 degrees)</p> <p>c. in December 2011, 12 of 21 days were out of compliance with facility policy (30 to 34 degrees)</p> <p>d. in January 2012, 5 of 18 days were out of compliance with facility policy (26 to 34 degrees)</p> <p>3. at 3:15 PM on 1/30/12, interview with staff members NA and NB indicated:</p> <p>a. the refrigerator temperature logs have documentation of many days per month that the temperature checks were out of compliance with the facility policy</p> <p>b. the daily checklist had an area for staff to document an "action for failed result" that had been implemented to bring the refrigerator back into correct temperature range, but only had one note of action documented in October, no documentation in November, one note in December and 3 days of notation of corrective action in January</p> <p>c. in most instances, staff was failing to note any adjustment to refrigerator controls to meet the 36 to 46 degree requirement for medications</p> <p>d. the medications currently in the pharmacy refrigerator have been jeopardized with temperatures reaching below freezing, thus compromising patient safety in receiving these medications</p>		<p>01/30/12 in response to documented erratic temperature control. In addition, on 2/17/12 the director purchased and put a digital probe thermometer into place in the medication refrigerator. The device is programmed to text the director and chairperson of the Safety Committee whenever the temperature varies from the pre-set, desired range. The director reinforced the importance of documenting the refrigerator temperatures on the refrigeration log on each business day at a staff meeting on 02/17/12. The Medical Executive Committee, and Board approved the changes 02/27/12. Monitoring Compliance The director monitors compliance with the policy revision by 100% audit of the refrigerator logs each month. Parkview Biomedical department inspects the facility refrigerators annually, and will report any problems to the director.</p>				

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Q0202	<p>416.49(b) RADIOLOGIC SERVICES (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.</p> <p>Based on document review and interview, the center failed to identify the consulting radiologist as part of the medical staff to supervise the ionizing radiology services for the facility.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 2-01-12 at 0900 hours, staff A1 was requested to provide documentation indicating that the fluoroscopic radiology services were supervised by a radiologist who was a member of the medical staff and none was provided prior to exit. During an interview on 2-01-12 at 0955 hours, staff A1 confirmed that the center lacked a radiologist that was a member of the medical staff to supervise the radiologic services. 	O0202	<p>Q202 – 416.49(b) Radiologic Services Plan of Correction The Director initiated the request for the Radiology consultant physician to be credentialed as a member of the medical staff. The credentialing body completed the credentialing process for Dr. Timothy Grissom, MD, director of Fort Wayne Radiology Consultant, and contractor to Inverness Surgery Center on 2/22/12. Dr. Grissom's credentials as a member of the medical staff to provide Inverness Surgery Center with supervision of radiologic services, were approved by the Medical Executive Committee on 2/27/12.</p> <p>Monitoring Compliance The director and/or designee will generate the renewal of credentials process for the contracted radiologic services supervisor every two years per the current facility credentialing process.</p>	02/27/2012			

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Q0221	<p>416.50(a)(1) NOTICE OF RIGHTS 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 center lacked a policy/procedure for ensuring notice of patient rights prior to the procedure and failed to ensure that the notice included 2 of 14 required elements.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. On 1-30-12 at 1015 hours, staff A1 was requested to provide a policy/procedure for patient rights notice to be provided to the patient prior to the start of the procedure and none was provided prior to exit. 2. Review of the patient's rights document Inverness Surgery Center Statement of Patient Rights failed to indicate the following: <ol style="list-style-type: none"> a. The facility must provide the patient and/or their representative upon request, a copy of the official State advanced directive forms b. The patient has the right to submit 	O0221	<p>Q221 416.50(a)(1) Notice of Rights Plan of Correction The Center director created a specific policy for the protection of patient rights, MR 08 Patient Rights Policy on 2/13/12. The policy specifies that the Center will provide the patient or patient's guardian verbal and written documentation of the patient rights in a language understandable to them on and before the date of surgery. The policy also indicates that the admitting office personnel of the Center will offer the patient or patient's guardian a copy of the Indiana State current advanced directive forms. The patient rights document kept in the Center and sent in the pre-operative packets was changed to include: 17. The patient has a right to file a grievance regarding the quality of care or services rendered. Contact the director at 260-434-3600. If the grievance is not handled to the patient's satisfaction, the Indiana State Department of Health can be contacted at (800)-246-8909 or at complaints@isdh.in.gov, 2 North Meridian Street, Indianapolis, Indiana, 46204 or through the</p>	02/29/2012			

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	<p>grievances regarding treatment or care that fails to be furnished.</p> <p>3. During an interview on 1-31-12 at 1300 hours, staff A1 confirmed that the center lacked a policy/procedure for ensuring notice of patient rights and confirmed that the statement of patient rights lacked two required elements.</p>		<p>office of Medicare Beneficiary Ombudsman at www.medicare.gov/navigation/help-and-support/filing-a-complaint-or-grievance.aspx 18. Information regarding advance directives (living will) from the state of Indiana, is offered to every patient. Please note that Inverness Surgery Center suspends advanced directives. Should the patient be transferred to a hospital, the document will be forwarded and the hospital will honor it. The director revised the policy dealing with advanced directives, PC 003 – Advanced Directives to include the use of Indiana State Advanced Directives and also to specify that the registrar will sticker the patient chart to indicate if he or she has an advanced directive in place. The policy revision requires that The pre-operative nurse must document when the patient does have advance directives in place, on the reverse side of the Pre-Operative record, in the nursing notes. The policies were reviewed and passed by the Medical Executive Committee and Board on 2/27/12, and reviewed with the staff on 2/29/12. In addition, the lobby wall plaque of the patient rights document and patient rights handout were revised to the above mentioned content on 2/29/12. Monitoring Compliance The director or designee will audit a percentage of charts as well as</p>		

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			the registration process, each month, to determine if the Center staff are properly offering Indiana State information about advanced directives, and documenting when advance directives are in desired by the patient.	

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Q0224	<p>416.50(a)(2) ADVANCE DIRECTIVES The ASC must comply with the following requirements:</p> <p>(i) Provide the patient or, as appropriate, the patient's 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, if requested, official State advance directive forms.</p> <p>(ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.</p> <p>(iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.</p> <p>Based on document review and interview, the facility failed to have a policy/procedure that expressed its position on advance directives and ensured the availability (upon request) of a copy of the State advanced directive forms.</p> <p>Findings:</p> <p>1. On 1-30-12 at 1015 hours, staff A1 was requested to provide a policy/procedure regarding Advance Directives and none was provided prior to exit.</p> <p>2. During an interview on 1-31-12 at</p>	O0224	<p>Q 224 416.50(a)(2) Advance Directives Plan of Correction The Center director created specific language for the handling of Advance Directives, documenting of Advance Directives in the medical record, and explaining how to offer information about Advance Directives in the PC 003 Advance Directives policy. The Patient Rights statement relating to advance directives was also changed to reflect the following:</p> <p>18. Information regarding advance directives (living will) from the state of Indiana, is offered to every patient. Please note that Inverness Surgery Center suspends advanced directives. Should the patient be transferred to a hospital, the document will be forwarded and</p>	02/29/2012	

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	1300 hours, staff A1 confirmed that the center lacked a policy/procedure for Advance Directives.		the hospital will honor it. The director revised the policy dealing with advanced directives, PC 003 – Advanced Directives to include the use of Indiana State Advanced Directives and also to specify that the registrar will sticker the patient chart to indicate if he or she has an advanced directive in place. The policy revision requires that The pre-operative nurse must document when the patient does have advance directives in place, on the reverse side of the Pre-Operative record, in the nursing notes. The policy was reviewed and passed by the Medical Executive Committee and Board on 2/27/12, and reviewed with the staff on 2/29/12. In addition, the Advance Directives information from the state of Indiana replaced the handouts about directives the Center supplies to patients, Also, the lobby wall plaque of the patient rights document and patient rights handout were revised to the above mentioned content on 2/29/12. Monitoring Compliance The director or designee will audit a percentage of charts as well as the registration process, each month, to determine if the Center staff are properly offering Indiana State information about advanced directives, and documenting when advance directives are in desired by the patient.		

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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 grievance policy/procedure failed to indicate criteria when a complaint will be treated as a grievance and failed to ensure documentation with timeframes for the existence, investigation, determination, and notice of the decision including the name of the center contact person, steps taken to investigate, and the date the process was completed.</p> <p>Findings:</p>	Q0225	<p>Q225 – 416.50(a)(3)(i),(v),(vi), (vii) Submission and Investigation of Grievances Plan of Correction</p> <p>The director created a new Grievance and a separate Complaint policy for the Center, ADM 012 - Grievance Policy, and ADM 032 - Compliant Resolution Policy on 02/18/12. The grievance policy establishes the definition of a grievance and details specific steps for documenting and managing a grievance. The policy steps include the method of communication of the grievance, the timeframes required for review of the grievance, and the timeframes required for response</p>	02/29/2012

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	<p>1. The facility policy/procedure Grievance/Complaint Filing Procedure (approved 3-09) lacked the following:</p> <p>a. criteria indicating when a complaint will be considered a grievance.</p> <p>b. a provision for notice of determination to include the name of the contact person at the center, steps taken to investigate, and the date the grievance process was completed.</p> <p>2. During an interview on 1-31-12 at 0915 hours, staff A1 confirmed that the policy/procedure failed to clearly identify criteria indicating when a complaint shall be treated as a grievance and failed to indicate required elements for the determination notice.</p>		<p>to the complainant. The policy also specifies the steps required to properly investigate the grievance, and details the parties to be involved in the process. The policy specifies how to document the handling of the grievance, managing written notice to the complainant, including names of contact personnel, and a description of steps taken to resolve the issue. The policy provides timeframes for providing the results of the process to the complainant, and the Center documentation of the process and completion of the handling of the grievance. The policy includes a description of the difference between a complaint and a grievance and describes specific timeframes for activities related to handling all grievances. The policy was reviewed and approved by the Medical Executive Committee and Board on 2/27/12. The Center staff was educated about the changes on 2/29/12. The patient rights signage in the lobby was changed to reflect the new verbiage. Monitoring Compliance The director and medical director will manage all grievances in the center to ensure the correct procedure and timeframes are maintained.</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 center failed to ensure a policy that included that all allegations of abuse, neglect, or mistreatment which are alleged to have occurred at the ASC will be documented and substantiated allegations will be reported to the State and/or the local authority.</p> <p>Findings:</p> <p>1. The policy/procedure Grievance/Complaint Filing Procedure (approved 1-12) failed to indicate a process for responding to allegations involving mistreatment, neglect, verbal, mental, sexual, or physical abuse alleged to have occurred at the ASC.</p> <p>2. Review of the policy/procedure Criteria for Reporting Abuse and/or Neglect (approved 1-12) failed to indicate that substantiated allegations which</p>	Q0226	<p>Q226 – 416.50(a)(3)(ii),(iii),(iv) Grievances – Mistreatment, Abuse, Neglect Plan of Correction The director revised the policy relating to the reporting of suspected abuse of any type, in policy RM 10 Criteria for Reporting Abuse of Neglect on 2/16/12. The revisions describe the steps to take in order to react to and report to allegations of abuse that may have occurred in the Center. The policy revision indicates the procedure for immediately notifying the Center leadership, and for notifying local authorities, and the State authorities once the claims have been substantiated. The policy was reviewed and approved by the Medical Executive Committee and the Board on 2/27/12. The staff was educated about the policy during the week of 2/27/12.</p> <p>Monitoring Compliance The Center director or designee will audit 100% of claims of any type abuse, mistreatment, or harassment</p>	02/29/2012

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	<p>occurred at the facility would be reported to the State and local authorities.</p> <p>3. During an interview on 1-31-12 at 0915 hours, staff A1 confirmed that the policy/procedures lacked the indicated provisions.</p>		<p>occurring in the Center.</p>	

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Q0228	<p>416.50(b)(1)(ii) EXERCISE OF RIGHTS - GRIEVANCES [The patient has the right to -] Voice grievances regarding treatment or care that is (or fails to be) furnished.</p> <p>Based on document review, the center failed to have a policy/procedure addressing the patient right to voice grievances regarding treatment or care they receive (or fail to receive.)</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-31-12 at 1015 hours, staff A1 was requested to provide documentation of a facility-approved policy that patients have a right to voice grievances regarding treatment or care they receive or fail to receive and no documentation was provided prior to exit. Review of the center document Inverness Surgery Center Statement of Patient Rights failed to indicate the patient right to voice grievances regarding treatment or care they fail to receive from the facility. 	O0228	<p>Q228 – 416.50(b)(1)(ii) – Exercise of Rights – Grievances Plan of Correction The director created a new Grievance Policy, ADM 012, and a Patient Rights Policy, MR 08 on 2/18/12 and 2/13/12 respectively. Both policies contain verbiage stating that all patients in the Center have the right to voice grievances about the care provided or not provided by Inverness. The policies were presented to and approved by the Medical Executive Committee and Board on 2/27/12. The changes were explained to the staff during the week of 2/27/12. Monitoring Compliance The Center director will maintain the policy corrections in accordance with state and federal law.</p>	02/29/2012			

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Q0241	<p>416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>Based on policy and procedure review, manufacturer's manual review, document review and staff interview, the infection control practitioner failed to ensure the contracted housekeeping staff provided the environmental cleaning services requested/required and failed to implement the policy related to sterilization cleaning and maintenance per the manufacturer's recommendations.</p> <p>Findings: 1. at 9:00 AM on 1/31/12, review of the policy and procedure "Housekeeping", PC 109, indicated: a. under "Policy", in item 4., it reads: "Supervision of cleaning in the non-restricted, semi-restricted areas will be supervised and inspected by the Director and the Housekeeping contract company." b. under "Policy", in item 6. A. j., it reads: "Floors will be cleaned with a clean mop-head furnished by a service at the end of the day..." c. under "Policy", in item 6. C. "Monthly Cleaning", it reads: "1.</p>	Q0241	<p>Q241 416-51(a) Sanitary Environment Plan of Correction The following items have been changed to bring us into compliance. The policy, PC 109 – Housekeeping was revised by the director to clarify the supervisory process of observing the cleaners quarterly and annually on 02/16/12. A cleaning log was created for use in auditing the cleaning process. The policy revisions included clarification of monthly, daily and semi-annual chores. The director also revised the existing cleaning log sheets. The log sheets now reflect the separate daily and weekly and longer time frame required duty lists on separate logs. The daily logs allow for daily housekeeper signatures and exact date by line item. The weekly cleaning logs allow for daily housekeeper signatures and exact date by line item. All cleaning log titles, headers, footers, and descriptors are now consistent through each page for each type of log. The use of daily and weekly cleaning logs now incorporate tasks formerly listed as monthly or semi-annually. Tasks are now either daily or weekly.</p>	02/29/2012

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	<p>Shelves are cleaned weekly..."</p> <p>d. under "Policy", in item 6. D. "Semi-Annual Cleaning", it reads: "1. Scrub sinks are thoroughly disinfected daily. Spray heads of faucets are taken off and disinfected."</p> <p>e. under "Policy", in item 6. F., it reads: "Annual walk thru inspections are completed."</p> <p>2. at 11:20 AM on 2/1/12, review of the document titled "Weekly Terminal Cleaning of Sterile Areas-Log" indicated:</p> <p>a. the form has blank areas for the "Week of" with a beginning date of the week and an ending date of the week to be noted by the housekeeping staff</p> <p>b. 3 forms were provided for review with 11/1/11 to 11/30/11 noted/documented at the top of the page; 12/1/11 to 12/31/11 on another; and 1/2/12 to 1/31/12 noted on the last form</p> <p>c. it cannot be determined that floors are cleaned daily (1. b. above) as the checklist only has one date (12/1/11) for the whole month of December noted/documented</p> <p>d. there is no documentation that would show that "Monthly cleaning" (as listed in 1. c. above) was completed</p> <p>e. there was no documentation by housekeeping staff that "Semi-Annual Cleaning" had been accomplished (as per 1. d. above)</p>		<p>The policy requires the Infection Control Chairperson to complete a quarterly audit of the cleaning process. The observer will use the new cleaning audit form to document observations of the housekeeper's habits per the revised policy.</p> <p>The director created a second policy, PC 118 – Cleaning the Amsco Eagle Series 3000 Sterilizer policy, to address the proper method of cleaning, using the correct products, and maintaining the Center autoclaves. The sterilizers will be cleaned and maintained on a daily, weekly, and monthly basis per the manufacturer requirements. The policy also designates the surgical technicians as the parties responsible for the daily, weekly, and monthly cleaning of the autoclaves, under the direction of the Infection Control Chairperson and to the requirements of the sterilizer manufacturer. The quarterly cleaning is designated to the facility biomechanical contractors, and includes the quarterly required cleaning and maintenance as described by the autoclave manufacturer. The policies were presented to and approved by the Medical Executive Committee and the Board on 2/27/12. The policy was introduced to the staff on 3/1/12.</p> <p>Monitoring Compliance The Infection Control Chairperson</p>				

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	<p>3. interview with staff member NC at 11:20 AM on 2/1/12 indicated:</p> <p>a. the form/log says "Weekly Terminal Cleaning", but is for daily cleaning and staff is not completing the form daily as expected</p> <p>b. it is unknown why the housekeeping staff only documents cleaning on one form in a monthly manner when daily cleaning is to be documented</p> <p>c. this staff member has observed cleaning staff on occasion, while remaining on site for 23 hours patients, but has never documented any of these observations that would indicate cleaning is being accomplished per facility requirements and per facility policy (listed as a policy requirement in 1. e. above)</p> <p>d. there is no documentation related to the "inspection" to be done by the Director as stated in the housekeeping policy (1. e. above)</p> <p>e. there is no documentation that indicates "annual walk thru inspections" are being completed as per the housekeeping policy (1. e. above)</p> <p>f. the policy is not clear as it reads in item 6. D. for "Semi-Annual Cleaning", to be scrubbed thoroughly and disinfected daily, but is in the semi annual area</p> <p>g. it is unclear if the second portion of 6. D where "spray heads of faucets are taken off and disinfected." is the semi annual portion, or not</p>		<p>will monitor the autoclave cleaning and maintenance process quarterly using the sterilizer maintenance log. Any exceptions to the policy will be reported to the director or designee.</p>				

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	<p>h. the housekeeping checklist does not have an area for the staff to indicate any of the Monthly or semi annual cleaning duties making it unclear if any of these have been performed in the past year</p> <p>4. at 9:00 AM on 1/31/12, review of the policy and procedure "Housekeeping", PC 109, indicated: a. on page two under C. "Monthly Cleaning", it reads: "...2. Sterilizer interiors are cleaned as recommended by the manufacturer."</p> <p>5. at 10:35 AM on 2/1/12, review of the Amsco "EAGLE SERIES 3000", manual section "4. Routine Maintenance", indicated: a. in section 4.1 "Daily...", it reads: "1. Clean chamber as follows: a. Wash inside of chamber and loading equipment with a mild detergent solution such as STERISs' Liquid-Jet or Sonic detergents. b. Rinse with tap water; dry with a lint-free cloth. c. Remove chamber drain strainer. Clean out lint and sediment; reverse flush under running water. d. Place strainer back in chamber drain" b. in section 4.2 "Weekly...", it reads: "1. Flush chamber drain as follows:...2. Check control and status signals as follows:...3. Flush steam generator..." c. in section 4.3 "Monthly...", it reads: "1. Place a few drops of heavy machine</p>			

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	<p>oil (SAE 20 or 30 motor oil) on chamber door hinge pins..."</p> <p>d. in section 4.4 "Quarterly...", it reads: "1. Grease door post as follows...2. Inspect door gasket...3. Have a qualified service person check jacket and, if equipped, steam generator safety valves."</p> <p>6. interview with staff members NB and NC at 10:35 AM on 2/1/12 indicated: a. the only portion of the manual that is being performed by staff at the facility is section 4.2 item 3. (flushing of the steam generator) and it is being done daily, not weekly b. it was thought that the local hospital maintenance/biomed staff are doing the other maintenance recommendations listed in the manual c. no detergent (such as the Steris Sonic product) are used when flushing the sterilizers</p> <p>7. interview with staff member NA at 1:40 PM on 2/1/12 indicated: a. the hospital maintenance staff are not performing the Amsco sterilizer manual maintenance recommendations b. currently, the policy is not implemented as relates to cleaning as per the recommendations of the manufacturer</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			
Q0263	<p>416.52(a)(3) ADMISSION ASSESSMENT - RECORD The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.</p> <p>Based on policy and procedure review, medical staff rules and regulations review, patient medical record review, and staff interview, the medical staff failed to ensure the implementation of facility policy and rules and regulations related to history and physical preparations prior to surgery for 3 of 16 patients. (N4, N8 and N9)</p> <p>Findings: 1. at 2:25 PM on 2/1/12, review of the medical staff rules and regulations, approved by the medical staff on 9/28/09, and by the governing board on 10/24/09, indicated: a. in item "IX.", it reads: "A pertinent history and physical examination shall be performed according to the Centers guidelines or concurrent with the admission of the patient. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed..." b. in item "XVII.", it reads: "All podiatry procedures shall be performed in conjunction with the regulations set by the Surgery Center and the Medical</p>	00263	<p>Q263 – 416.52(a)(3) Admission Assessment Record Plan of Correction The director revised the policy MR 003 History & Physical, to remove the verbiage "if applicable" relating to the "change" or "no change" statement in the policy on 2/15/12. The policy now reads that if the H&P is done prior to the surgery date, it must be updated on the day of surgery. If not changes are required, the update is marked as such, with the phrase "no change". The policy revision was submitted to the Medical Executive Committee and Board and approved. The director educated the staff during the week if 2/27/12. The medical director informed the physicians in the center of the necessity to comply with the policy. The team posted signage about the "H&P" rules in the physician areas of the Center to remind physicians to comply. Monitoring Compliance The director or designee will sample random medical records each month and conduct a review for correct use, updating, and notating on the History and Physical form. Mary Kay Sterrett, the facility third-party medical records review consultant, was informed of the new policy, the</p>	02/29/2012			

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	<p>Executive Committee. An adequate history and physical shall be performed by a physician for each podiatry patient prior to surgery."</p> <p>2. at 11:55 AM on 2/1/12, review of the policy and procedure "History and Physical", MR 03, indicated:</p> <p>a. under "Procedure", it reads: "A. A medical History & Physical (H&P) will be done on each patient prior to the date of surgery or by the surgeon and/or anesthesiologist upon admission to the facility...2. H & P's done outside the facility must be performed within 30 days from the date of surgery. The surgeon must also review and indicate any changes to the patient's status or no change if applicable on the date of surgery..."</p> <p>b. under "Procedure", it reads: "B. In the case of podiatry or ophthalmology cases, the anesthesiologist will complete the H&P portion after examining the patient."</p> <p>3. review of patient medical records through out the survey process of 1/30/12 to 2/1/12 indicated:</p> <p>a. pt. N4:</p> <p>A. had a dictated H&P done on 11/21/10</p> <p>B. had surgery on 11/22/10</p> <p>C. had authentication (signature and</p>		policy revision, re-education, and expectations by the director at the quarterly medical records meeting.	

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	<p>date only) by the physician on 11/22/10 on a blank one page "History" form in the patient's chart</p> <p>D. lacked a note by the physician as to whether there were any changes to the previous day's dictated H & P prior to the patient's surgery</p> <p>b. pt. N8: A. lacked completion of the "Physical Examination" portion of the one page "History" form on 7/5/11 (the form was authenticated by the practitioner on 7/5/11, but lacked a physical exam--the dictated H & P in the chart was dated 2/9/11 with a fax date of 6/22/11)</p> <p>c. pt. N9: A. had surgery on 8/1/11 for "Arthroplasty 2nd toe right foot..." by a podiatrist B. had the one page H & P form completed by the podiatrist on 8/1/11 C. had a H & P form from the podiatrist's office dated 7/27/11 that had a portion at the bottom to be completed by the anesthesiologist that was blank</p> <p>4. interview with staff member NB at 3:30 PM on 2/1/12, indicated: a. the policy related to H & P's (MR 03), should not have the language "if applicable" if there is no change to a H&P done prior to the date of surgery, an</p>			

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S0000	<p>update must be done and indicate change, or no change</p> <p>b. pt. N9 should have had a H&P done by the anesthesiologist prior to surgery, the podiatrist was not to have completed the one page H&P form prior to the patient's surgery</p> <p>The visit was for a licensure survey.</p> <p>Facility Number: 004581</p> <p>Survey Date: 1-30-12 to 2-01-12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 03/08/12</p>	S0000	Agreed				

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S0300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>Based on document review and interview, the center failed to develop and maintain its quality assessment and improvement program to ensure objective ongoing monitoring of all services and important aspects of care.</p> <p>Findings:</p> <p>1. The Quality Improvement Plan (approved 8-11) indicated the following: "The Center's Medical Executive Committee (MEC) shall review and approve indicators to assure that indicators are not duplicated [and] that an appropriate number of indicators are chosen for each aspect of care." The Plan lacked a provision for ensuring that contracted services were provided in a</p>	S0300	<p>Tag S 300 410 IAC 3015-2.4-2(a) Quality Assessment & Improvement</p> <p><i>"This Rule is not met as evidenced by: Based on document review and interview, the center failed to develop and maintain its quality assessment and improvement program to ensure objective ongoing monitoring of all services and important aspects of care."</i></p> <p>FINDINGS #1</p> <p><i>"The Quality Improvement Plan (approved 8-11) indicated the following: "The Center's Medical Executive Committee (MEC) shall review & approve indicators to assure that indicators are not duplicated and that an appropriate number of indicators are chosen for each aspect of care." The Plan lacked a provision for ensuring that contracted services were provided in a safe and effective manner."</i></p>	03/01/2012			

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	<p>safe and effective manner.</p> <p>2. The 15 page Quality Improvement Committee Reporting Form (approved 8-11) failed to prioritize the scope of data collected and reported, failed to identify specific service standards applied to many reported aspects of care and services, and failed to ensure that center indicator performance could be reviewed over multiple periods for ongoing monitoring of each quality indicator or aspect of care.</p> <p>3. The Contractor Service Evaluation Report failed to indicate specific, objective and meaningful standards for evaluating each service, failed to indicate sampling frequency for standards applied to each provider, and failed to ensure that provider indicator performance could be reviewed over multiple periods.</p> <p>4. During an interview on 2-01-2012 at 1215 hours, staff A1 confirmed that the QI Plan lacked the indicated provision. Staff A1 indicated that the QI reports lacked specific, objective standards and failed to ensure the ongoing evaluation of each service. Staff A1 confirmed that the</p>		<p>RESPONSE #1</p> <p>The "Quality Improvement Committee Data Collection Form" clearly lists contractor services and this is tracked monthly and reported quarterly. The Quality Improvement Plan has been revised as follows to match the practice of the QI Committee Data Collection Form:</p> <p>Old verbiage:</p> <p>II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center based on the Center's scope of service. These may be chosen by the Center or as a means to meet regulatory requirements.</p> <p>New verbiage (red ink):</p> <p>II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center</p>				

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	QI reports needed simplification to ensure that program objectives were met.		<p>based on the Center's scope of service. These may be chosen by the Center or as a means to meet regulatory requirements. They will be approved by the appropriate committee which will include the Quality Improvement Committee, Medical Executive Committee, and the Governing Body. The important aspects of care will include, but is not limited to, the following:</p> <p>A. All services, including services furnished by a contractor (tracked via the "Contractor Services Evaluation Form")</p> <p>B. All functions (tracked via the "Quality Improvement Data Collection Form"), including, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. Discharge and transfer of patients 2. Infection Control 3. Medication errors 4. Response to patient emergencies <p>C. All services performed in the center with regard to appropriateness of diagnoses & treatment as it relates a standard of care and anticipated or expected outcomes. (Tracked via peer review and chart audits.)</p> <p>FINDINGS #2 <i>"The 15 page Quality Improvement Committee Reporting Form (approved 8-11) failed to prioritize the scope of data collected and reported, failed to identify specific service</i></p>		

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			<p><i>standards applied to many reported aspects of care and services, and failed to ensure that center indicator performance could be reviewed over multiple periods for ongoing monitoring of each quality indicator or aspect of care."</i></p> <p>RESPONSE #2 The QI Committee Data Collection Form is a tool used document, track, and report pertinent information. All important aspects of care and service are tracked monthly and reported quarterly. The Data Collection Form has always prioritized these aspects of care as follows:</p> <p>1. Reportable Events (includes surgical/procedure events, product/device events, patient protection events, care management events, and criminal events) as defined by the ISDH.</p> <p>2. Adverse Events (includes post procedure bleeds, perforations, medication errors, reversal agents used, narcotic counts incorrect, falls, code blues, patient emergencies, any other sentinel event not otherwise listed (includes transfers to hospital, unscheduled treatment within 72 hours of procedure, and AMA/elopement) And so on.</p> <p>The area of Contract Services is #15 on the QI Data Collection Form and includes a review of</p>		

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			<p>expiration dates of contracts, quarterly review of performance & indicators, as well as an annual review of indicators. Detailed information for each contracted service is found on the "Contractor Service Evaluation Report". We have revised that form to include four quarters on the report form. This allows anyone reviewing the form to see trends without reviewing the quarterly reports.</p> <p>FINDINGS #3 "The Contractor Service Evaluation Report failed to indicate specific objective and meaningful standards for evaluating each service, failed to indicate sampling frequency for standards applied to each provider, and failed to ensure that provider indicator performance could be reviewed over multiple periods."</p> <p>RESPONSE #3 The "Contractor Service Evaluation Report" has objective standards for each contractor that the Center utilizes. These indicators are measurable and are used to ensure that the contractor is meeting the needs of the Center. This is reported quarterly via the QI Committee Data Collection Form. While most of the indicators will remain the same for a year at a time, indicators can be changed as needed to evaluate the service. Using the laundry contract service</p>		

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			<p>as an example, if there are three quality indicators for this service and they are being met 100% of the time; however the staff is reporting a musty odor to the clean linen that is being delivered for the past two weeks. That would start out as an incident report in order to open up an investigation as to why we have seen a change in the quality of the linen being delivered to the Center and may become a new quality indicator if adequate explanation is not given. Each contractor service is reviewed annually and includes review of the contract, whether to renew the contract, assignment of indicators, and whether the contractor is meeting the needs of the Center. The "Contract Service Evaluation Report" was revised, utilizing the format provided by the surveyor, to include one year's worth of data evaluation to simplify the evaluation process. This information is reported through the QI Committee, Medical Executive Committee, and Governing Body for evaluation on a quarterly basis and reviewed for contract renewal on an annual basis to ensure ongoing compliance.</p> <p>These changes were presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were educated of the</p>		

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			changed by 3-1-12.	

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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 center failed to ensure that contracted services were evaluated through its quality assessment and improvement program.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Improvement Plan (approved 8-11) failed to indicate a process for documenting and reporting the ongoing evaluation of contracted services and failed to indicate the frequency for evaluation sampling of each service using its Contractor Service Evaluation Report.</p> <p>2. The Contractor Service Evaluation Report failed to indicate specific, objective and meaningful standards for evaluating each service and failed to simplify and integrate the separate categories of quality identifier, expectation of quality identifier,</p>	S0310	<p>Tag S 310 410 IAC 3015-2.4-2(a) (1) Quality Assessment & Improvement</p> <p>"This Rule is not met as evidenced by: Based on document review and interview, the center failed to ensure that contracted services were evaluated through its quality assessment and improvement program."</p> <p>FINDINGS #1</p> <p><i>"The policy/procedure Quality Improvement Plan (approved 8-11) failed to indicate a process for documenting and reporting the ongoing evaluation of contracted services and failed to indicate the frequency for evaluation sampling of each service using its Contractor Service Evaluation Report."</i></p> <p>RESPONSE #1</p> <p>The "Quality Improvement Committee Data Collection Form" clearly indicates that evaluation of contracted services is ongoing and is reported quarterly. The "Quality Improvement Plan" has</p>	03/01/2012			

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	<p>threshold, and compliance of threshold level into a discrete service standard. It could not be determined what the values "100%" and " Threshold 100%" reflected for the majority of services listed and reported on. The report failed to ensure that provider indicator performance could be reviewed over multiple periods for ongoing monitoring each service.</p> <p>3. The 15 page Quality Improvement Committee Reporting Form 3rd Quarter 2011 lacked the quality indicators applied to contracted service providers. The report listed the medical records (MR) and pharmacist consultants and failed to indicate that the MR consultant visited on 7-19-11 and that the pharmacist failed to visit during the 3rd quarter and lacked an explanation for the variance.</p> <p>4. During an interview on 2-01-12 at 1215 hours, staff A1 confirmed that the QI Contractor Report and QI Committee Report lacked measureable and objective standards and failed to ensure the ongoing evaluation of each service.</p>		<p>been revised as follows to provide clarity and to match the practice of the QI Committee Data Collection Form: Old verbiage: II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center based on the Center's scope of service. These may be chosen by the Center or as a means to meet regulatory requirements.</p> <p>New verbiage (red ink): II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center based on the Center's scope of service. These may be chosen by the Center or as a means to meet regulatory requirements. They will be approved by the appropriate committee which will include the</p>		

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			<p>Quality Improvement Committee, Medical Executive Committee, and the Governing Body. The important aspects of care will include, but is not limited to, the following:</p> <p>A. All services, including services furnished by a contractor (tracked via the "Contractor Services Evaluation Form")</p> <p>B. All functions (tracked via the "Quality Improvement Data Collection Form"), including, but not limited to, the following:</p> <ol style="list-style-type: none"> 1. Discharge and transfer of patients 2. Infection Control 3. Medication errors 4. Response to patient emergencies <p>C. All services performed in the center with regard to appropriateness of diagnoses & treatment as it relates a standard of care and anticipated or expected outcomes. (Tracked via peer review and chart audits.)</p> <p>FINDINGS #2 "Contractor Service Evaluation Report" failed to indicate specific, objective and meaningful standards for evaluating each service and failed to simplify and integrate the separate categories of quality identifier, expectation of quality identifier, threshold, and compliance of threshold level into a discrete service standard. It could not be determined what the</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	
			<p><i>values "100%" and "Threshold 100%" reflected for the majority of services listed and reported on. The report failed to ensure that provider indicator performance could be reviewed over multiple periods for ongoing monitoring each service."</i></p> <p>RESPONSE #2</p> <p>The "Contractor Service Evaluation Report" has objective standards for each contractor that the Center utilizes. These indicators are measurable and are used to ensure that the contractor is meeting the needs of the Center. This is reported quarterly via the QI Committee Data Collection Form. While most of the indicators will remain the same for a year at a time, indicators can be changed as needed to evaluate the service. Each contractor service is reviewed annually and includes review of the contract, whether to renew the contract, assignment of indicators, and whether the contractor is meeting the needs of the Center. The "Contract Service Evaluation Report" was revised to include one year's worth of data evaluation to simplify the evaluation process for trends. This information is reported through the QI Committee, Medical Executive Committee, and Governing Body for evaluation on a quarterly basis and reviewed for contract renewal on an annual basis.</p>		

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			<p>Old Version</p> <p>CONTRACTOR DESCRIPTION OF SERVICE PROVIDED</p> <p>QUALITY IDENTIFIER EXPECTATION OF QUALITY IDENTIFIER THRESHOLD COMPLIANCE OF THRESHOLD LEVEL</p> <p>RECOMMEND ACTIONS</p> <p>ESCO Fire/Safety Online monitoring of facility security and fire systems When "trouble alarms" are activated a security officer is to respond to check the facility. Response time will be within 30 minutes of the "trouble alarm" as evidenced by ESCO reports monitored by clinical supervisor. 100%</p> <p>Rose Pest Control Pest Control Company will send a representative when Center reports increased pests, i.e. spiders, etc. Representative will respond within 1 to 2 business days. Clinical supervisor will track response time through incident reports. 100%</p> <p>Revised Version</p> <p>CONTRACTOR DESCRIPTION OF SERVICE PROVIDED</p>	

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			<p>QUALITY IDENTIFIER EXPECTATION OF QUALITY IDENTIFIER THRESHOLD COMPLIANCE OF THRESHOLD LEVEL RECOMMEND ACTIONS Qtr 1 Qtr 2 Qtr 3 Qtr 4</p> <p>ESCO Fire/Safety Online monitoring of facility security and fire systems When "trouble alarms" are activated a security officer is to respond to check the facility. Response time will be within 30 minutes of the "trouble alarm" as evidenced by ESCO reports monitored by clinical supervisor. 100%</p> <p>Rose Pest Control Pest Control Company will send a representative when Center reports increased pests, i.e. spiders, etc. Representative will respond within 1 to 2 business days. Clinical supervisor will track response time through incident reports. 100%</p>	

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			<p>FINDINGS #3 <i>"The 15 page Quality Improvement Committee Reporting Form 3 rd Quarter 2011 lacked the quality indicators applied to contracted service providers. The report listed the medical records (MR) and pharmacist consultants and failed to indicate that the MR consultant visited on 7-19-11 and that the pharmacist failed to visit during the 3 rd quarter and laced an explanation for the variance."</i></p> <p>RESPONSE #3 The quality indicators for each contracted service are found on the "Contract Service Evaluation Report" The "QI Committee Reporting Form" has "Contracted Services" as item #15. The following verbiage was added: "See Contract Service Evaluation Report" for details" to this section. The director of the Center has developed an "Event Calendar" that includes all events pertinent to the Center and the months in which they are to occur to ensure that the Center is performing the required evaluations of service, drills, etc. in order to provide a safe environment for staff, patients and visitors.</p> <p>FINDINGS #4 <i>"During an interview on 2-1-12 at 12:15 hours, staff A1 confirmed that the QI Contractor</i></p>		

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			<p>Report and QI Committee Report lacked measurable and objective standards and failed to ensure that ongoing evaluation of each service.”</p> <p>Response #4 See responses above. These changes were presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were educated on the changes effective 3-1-12. Monitoring for ongoing compliance will occur with the quarterly Quality Improvement Committee meetings using the QI Data Collection Form.</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 center quality assessment and improvement program lacked a policy/procedure indicating 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"> On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating the events to be reported to the Indiana State Department of Health and none was provided prior to exit. The policy/procedure Completion and Routing of Incident Reports (approved 1-12) and Risk Identification, Correction, and Follow-Up (approved 1-12) failed to indicate the events to be reported to the department. During an interview on 2-01-12 at 0945 hours, staff A1 confirmed that the policy/procedure failed to identify the reportable events indicated by state law. 	S0332	<p>Tag S 332 410 IAC 3015-2.4-2.2(a)(1) Quality Assessment & Improvement</p> <p>"This Rule is not met as evidenced by: Based on document review and interview, the center quality assessment and improvement program laced a policy/procedure indicating the reportable events identified by State law 410 IAC 15-2.4-2.2 Reportable Events." FINDINGS #1 "On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating the events to be reported to the Indiana State Department of Health and none was provided prior to exit." FINDINGS #2 "The policy/procedure Completion and Routing of Incident Reports (approved 1-12) and Risk Identification, Correction, and Follow-up (approved 1-12) failed to indicate the events to be reported to the department." FINDINGS #3 "During an interview on 2-1-12 at 0945 hours, staff A1 confirmed that the policy/procedure failed to identify the reportable events indicated by state law." RESPONSE 1 - 3 The "Quality Improvement Committee Data Collection Form" clearly lists the "Reportable events as defined by the Indiana State Department of Health" beginning with Item #1 "Reportable Events" which include "A-Surgical/Procedure Events, B-Product/device events, C-Patient protection events,</p>	03/01/2012	

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			D-Care management events, E-Environmental events, and F-Criminal Events", and Item #2 "Adverse Events". The Quality Improvement Plan was revised under the Important Aspects of Care and Service to include the required verbiage and to match the practice of the QI Committee Data Collection Form. Old verbiage: II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center based on the Center's scope of service. These may be chosen by the Center or as a means to meet regulatory requirements. New verbiage (red ink): II. IMPORTANT ASPECTS OF CARE AND SERVICE are areas that are chosen to be monitored and evaluated because of their importance to either the quality of care provided to the patient, the quality of safety for patients, staff, or the facility, the quality of the control of infections to patients and staff, or the quality of the staff in their abilities to meet the needs of our patients and the Center based on the Center's scope of service. These may be chosen by		

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			<p>the Center or as a means to meet regulatory requirements (including all reportable events as identified by the Indiana State Department of Health, Centers for Medicare/Medicaid Services, and/or other applicable regulatory agencies. They will be approved by the appropriate committee which will include the Quality Improvement Committee, Medical Executive Committee, and the Governing Body. The important aspects of care will include, but is not limited to, the following: A. All services, including services furnished by a contractor (tracked via the "Contractor Services Evaluation Form") B. All functions (tracked via the "Quality Improvement Data Collection Form"), including, but not limited to, the following: 1. Discharge and transfer of patients 2. Infection Control 3. Medication errors 4. Response to patient emergencies C. All services performed in the center with regard to appropriateness of diagnoses & treatment as it relates a standard of care and anticipated or expected outcomes. (Tracked via peer review and chart audits.) Verbiage was also incorporated into Policy EC 46 "Reportable / Sentinel Events Policy", Policy RM 01 "Completion and Routing of Incident Reports", and Policy RM 03 "Risk Identification, Correction, and Follow-up" to detail what is a reportable event,</p>	

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			reporting and documentation, and time frames required. These changes were presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were educated on the changes effective 3-1-12. Ongoing monitoring of compliance will occur through the Quality Improvement Committee using the QI Data Collection Form.		

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S0414	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1)</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>Based on infection control plan and meeting minute review, document review, and interview, the facility failed to ensure that a physician, or representative from the medical staff, was a member of the infection control committee.</p> <p>Findings: 1. at 11:00 AM on 1/31/12, review of the "VI. Infection Control Plan", indicated: a. under the section "Infection Control</p>	S0414	<p>Tag S 414 410 IAC 15-2.5-1(f) (1) Infection Control Program "This Rule is not met as evidenced by: Based on infection control plan and meeting minute review, document review, and interview, the facility failed to ensure that a physician, or representative from the medical staff, was a member of the infection control committee." FINDINGS #1 "At 11:00 AM on 1/31/12, review of the "VI. Infection Control Plan", indicated:</p>	03/01/2012

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	<p>Committee:", it reads: "Infection Control Committee will be chaired by the Center's Infection Preventionist. The Infection Preventionist will seek out and appoint appropriate staff members to be part of the Infection Control (IC) Committee..."</p> <p>2. at 11:00 AM on 1/31/12 , review of the infection control meeting minutes indicated:</p> <p>a. the infection control committee met on 4/14/11, 5/16/11, 6/27/11, and 10/19/11 (a sign in page for an August 11, 2011 meeting was included, but had no signatures on the document)</p> <p>b. there was no representative from the medical staff present at any of the meetings held in 2011</p> <p>3. A typed document provided on 1/30/12 indicated the Infection Control Committee members included 3 RNs (registered nurses), 1 secretary, 1 Surgical tech, and 1 Endoscopy tech</p> <p>4. a hand written "Infection Control Committee" member listing provided on 2/1/12, included a physician name</p> <p>5. interview at 10:30 AM on 1/31/12 with staff member NB, and at 12:45 PM on 1/31/12 with staff member NA, indicated:</p> <p>a. it was determined at the November</p>		<p>a. under the section "Infection Control Committee:" it reads: "Infection Control Committee will be chaired by the Center's Infection Preventionist. The Infection Preventionist will seek out and appoint appropriate staff members to be part of the Infection Control (IC) Committee..." FINDINGS #2 "At 11:00 AM on 1/31/12, review of the infection control meeting minutes indicated: a. the infection control committee met on 4/14/11, 5/16/11, 6/27/11, and 10/19/11 (a sign in page for an August 11, 2011 meeting was included, but had no signatures on the document) b. there was no representative from the medical staff present at any of the meetings held in 2011"</p> <p>FINDINGS #3 "A typed document provided on 1/30/12 indicated the Infection Control Committee members included 3 RNs (registered nurses), 1 secretary, 1 surgical tech, and 1 Endoscopy tech." FINDINGS #4 "A hand written "Infection Control Committee" member listing provided on 2/1/12, included a physician name." FINDINGS #5 "Interview at 10:30 AM on 1/31/12 with staff member NB, and at 12:45 PM on 1/31/12 staff member NA, indicated: a. it was determined at the November 28, 2011 Medical Executive Committee meeting that one of the physicians (listed on the document in 4. above) was</p>		

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	28, 2011 Medical Executive Committee meeting that one of the physicians (listed on the document in 4. above) was named/appointed to participate on the infection control committee b. no physician was present at the meetings of 2011		named/appointed to participate on the infection control committee b. no physician was present at the meetings of 2011 .” RESPONSE 1 - 5 The Center had appointed & approved Dr. Parikh from the Medical Executive Committee to serve on the Infection Control Committee on November 28, 2011. The next Infection Control Committee meeting was held on 2-16-12, in which Dr. Parikh was present as documented in the meeting minutes. The Infection Control Plan was revised to include the following verbiage: “A physician from the Medical Executive Committee will serve on the IC Committee.” The Infection Control Committee roster was revised to include Dr. Parikh as a member. These changes were presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were educated on the changes effective 3-1-12. Ongoing monitoring for compliance will occur by the Infection Control Committee Chair documenting attendance on the appropriate roster sign in sheets at each IC Committee meeting.		

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S0454	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(2)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(2) Written policies and procedures must be available and followed by personnel responsible for sterilizing equipment and supplies, including, but not limited to, the following:</p> <p>(A) Minimum time and temperature for processing various size bundles and packs.</p> <p>(B) Instructions for loading, operating, cleaning, and maintaining sterilizers.</p> <p>(C) Instructions for cleaning packaging, storing, labeling, and dispensing of sterile supplies.</p> <p>(D) Procedure for maintaining and recording the particular sterilizing cycle.</p> <p>(E) Sterilization of heat labile reusable equipment.</p> <p>Based on policy and procedure review, manufacturer's manual review, and interview, the infection control preventionist failed to implement the policy related to sterilization cleaning and maintenance per the manufacturer's recommendations.</p>	S0454	<p>Tag S 454 410 IAC 15-2.5-1(g)(2) Infection Control Program</p> <p>"This Rule is not met as evidenced by: Based on policy & procedure review, manufacturer's manual review, and interview, the infection control Preventionist failed to implement the policy related to sterilization cleaning</p>	03/01/2012

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	<p>Findings:</p> <p>1. at 9:00 AM on 1/31/12, review of the policy and procedure "Housekeeping", PC 109, indicated:</p> <p>a. on page two under C. "Monthly Cleaning", it reads: "...2. Sterilizer interiors are cleaned as recommended by the manufacturer."</p> <p>2. at 10:35 AM on 2/1/12, review of the Amsco "EAGLE SERIES 3000", manual section "4. Routine Maintenance", indicated:</p> <p>a. in section 4.1 "Daily...", it reads: "1. Clean chamber as follows: a. Wash inside of chamber and loading equipment with a mild detergent solution such as STERISs' Liquid-Jet or Sonic detergents. b. Rinse with tap water; dry with a lint-free cloth. c. Remove chamber drain strainer. Clean out lint and sediment; reverse flush under running water. d. Place strainer back in chamber drain"</p> <p>b. in section 4.2 "Weekly...", it reads: "1. Flush chamber drain as follows:...2. Check control and status signals as follows:...3. Flush steam generator..."</p> <p>c. in section 4.3 "Monthly...", it reads: "1. Place a few drops of heavy machine oil (SAE 20 or 30 motor oil) on chamber door hinge pins..."</p> <p>d. in section 4.4 "Quarterly...", it reads: "1. Grease door post as follows...2.</p>		<p>and maintenance per the manufacturer's recommendations."</p> <p>FINDINGS #1 "at 9:00 AM on 1/31/12, review of the policy and procedure "Housekeeping", PC 109, indicated:a. on page two under C. "Monthly Cleaning", it reads: "...2. Sterilizer interiors are cleaned as recommended by the manufacturer."."</p> <p>FINDINGS #2 "at 10:35 AM on 2/1/12, review of the Amsco "EAGLE SERIES 3000", manual section "4. Routine Maintenance", indicated:a. in section 4.1 "Daily...", it reads: "1. Clean chamber as follows: a. Wash inside of chamber and loading equipment with a mild detergent solution such as STERISs' Liquid-Jet or Sonic detergents. b. Rinse with tap water; dry with a lint-free cloth. c. remove chamber drain strainer. Clean out lint and sediment; reverse flush under running water. d. Place strainer back in chamber drain"b. in section 4.2 "Weekly...", it reads: "1. Flush chamber drain as follows:...2. Check control and status signals as follows:...3. Flush steam generator..." c. in section 4.3 "Monthly...", it reads: "1. Place a few drops of heavy machine oil (SAE 20 or 30 motor oil) on chamber door hinge pins..." d. in section 4.4 "Quarterly...", it reads: "1. Grease door post as follows...2. Inspect door gasket...3. have a qualified service person check jacket and,</p>				

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	<p>Inspect door gasket...3. Have a qualified service person check jacket and, if equipped, steam generator safety valves."</p> <p>3. interview with staff members NB and NC at 10:35 AM on 2/1/12 indicated: a. the only portion of the manual that is being performed by staff at the facility is section 4.2 item 3. (flushing of the steam generator) and it is being done daily, not weekly b. it was thought that the local hospital maintenance/biomed staff are doing the other maintenance recommendations listed in the manual c. no detergent (such as the Steris Sonic product) are used when flushing the sterilizers</p> <p>4. interview with staff member NA at 1:40 PM on 2/1/12 indicated: a. the hospital maintenance staff are not performing the Amsco sterilizer manual maintenance recommendations b. currently, the policy is not implemented as relates to cleaning as per the recommendations of the manufacturer</p>		<p>if equipped, steam generator safety valves."</p> <p>FINDINGS #3"interview with staff members NB and NC at 10:35 AM on 2/1/12 indicated:a. the only portion of the manual that is being performed by staff at the facility is section 4.2 item 3. (flushing of the steam generator) and it is being done daily, not weekly b. it was thought that the local hospital maintenance/biomed staff are doing the other maintenance recommendations listed in the manual c. no detergent (such as the Steris Sonic product) are used when flushing the sterilizers"</p> <p>FINDINGS #4"interview with staff member NA at 1:40 PM on 2/1/12 indicated:a. the hospital maintenance staff are not performing the Amsco sterilizer manual maintenance recommendationsb. currently, the policy is not implemented as relates to cleaning as per the recommendations of the manufacturer"</p> <p>FINDINGS #5"Interview at 10:30 AM on 1/31/12 with staff member NB, and at 12:45 PM on 1/31/12 staff member NA, indicated: a. it was determined at the November 28, 2011 Medical Executive Committee meeting that one of the physicians (listed on the document in 4. above) was named/appointed to participate on the infection control committeeb. no physician was present at the meetings of 2011 ."</p> <p>RESPONSE 1 - 5 The Director</p>		

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			<p>created a policy, PC 118 – Cleaning the Amsco Eagle Series 3000 Sterilizer policy, to address the proper method of cleaning, using the correct products, and maintaining the Center autoclaves. The sterilizers will be cleaned and maintained on a daily, weekly, and monthly basis per the manufacturer requirements. The policy also designates the surgical technicians as the parties responsible for the daily, weekly, and monthly cleaning of the autoclaves, under the direction of the Infection Control Chairperson and to the requirements of the sterilizer manufacturer. The quarterly cleaning is designated to the facility biomechanical contractors, and includes the quarterly required cleaning and maintenance as described by the autoclave manufacturer. The policies were presented to and approved by the Medical Executive Committee and the Board on 2/27/12. The policy was introduced to the staff on 3/1/12. Monitoring for ongoing compliance will occur by the Infection Control Committee Chair reviewing the cleaning logs and report quarterly in the Infection Control Committee meetings to ensure compliance.</p>	

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S0616	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(3)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(3) The center shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the center and medical staff policies.</p> <p>Based on document review and interview, the center failed to ensure that entries in the medical record (MR) are authenticated as allowed by center and medical staff policies.</p> <p>Findings:</p> <p>1. On 1-30-12 at 1015, staff A1 was requested to provide documentation indicating that electronic authentication by practitioners was approved by the governing body and none was provided prior to exit.</p> <p>2. The policy/procedure Guidelines for Maintaining the Medical Record as a</p>	S0616	<p>Tag S 616 410 IAC 15-2.5-3(c)(3) Medical Records, Storage, & Admin</p> <p>"Based on document review and interview, the center failed to ensure that entries in the medical record (MR) are authenticated as allowed by center and medical staff policies."</p> <p>FINDINGS #1 "On 1-30-12 at 1015, staff A1 was requested to provide documentation indicating that electronic authentication by practitioners was approved by the governing body and none was provided prior to exit."</p> <p>FINDINGS #2 "The policy/procedure Guidelines for Maintaining the Medical Record as a Medical-legal</p>	03/01/2012	

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	<p>Medical-legal Document (approved 1-12) lacked a provision for electronic (computer) authentication of MR entries.</p> <p>3. The Medical Staff Rules and Regulations (approved 10-09) failed to indicate that electronic authentication was authorized by the governing body.</p> <p>4. Review of medical records for patients N1, N4, and N12 indicated electronic authentication by the physician.</p> <p>5. During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the center lacked a policy/procure and medical staff rule regarding electronic authentication of entries in the MR by the medical staff.</p>		<p>Document (approved 1-12) lacked a provision for electronic (computer) authentication of MR entries."</p> <p>FINDINGS #3 "The Medical Staff Rules and Regulations (approved 10-09) failed to indicate that electronic authentication was authorized by the governing body."</p> <p>FINDINGS #4 "Review of medical records for patients N1, N4, and N12 indicated electronic authentication by the physician."</p> <p>FINDINGS #5 "During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the center lacked a policy/procure and medical staff rule regarding electronic authentication of entries in the MR by the medical staff."</p> <p>RESPONSE 1 – 5 Policy MR 01 "Documentation: Charting & Charts" was revised to include the following verbiage: "Stamps of the physician signature or date-time are not permitted in the medical record." and "Electronic physician signatures are permitted as part of the Parkview patient chart completion, post-procedure or after the day of service." This policy change was approved by the Medical Executive Committee and the Governing Body</p>		

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			on 2-27-12. Physician offices which had previously been found to send documents with electronic signatures were educated that those will no longer be accepted. Staff members were educated regarding the policy change and the policy was implemented on 3-1-12.	

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S0618	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(4)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(4) Medical records must be retained in their original or legally reproduced form as required by federal or state law.</p> <p>Based upon document review and interview, the center failed to ensure that documents in the medical record (MR) will be maintained for at least the minimum period of 7 years per current State law (IC 16-39-7-1).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating the length of time that MR documents were retained and none was provided prior to exit. On 2-01-12 at 1145 hours, staff #A1 confirmed that the center lacked a policy/procedure indicating how long the patient records will be kept. 	S0618	<p>Tag S 618 410 IAC 15-2.5-3(c)(4) Medical Records, Storage, & Admin</p> <p>This RULE is not met as evidenced by: "Based upon document review and interview, the center failed to ensure that documents in the medical record (MR) will be maintained for at least the minimum period of 7 years per current State law (IC 16-39-7-1).."</p> <p>FINDINGS #1 "On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating the length of time that MR documents were retained and none was provided prior to exit.."</p> <p>FINDINGS #2 "On 2-01-12 at 1145 hours, staff #A1 confirmed that the center lacked a policy/procedure indicating how long the patient records will be</p>	03/01/2012	

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			<p>kept."</p> <p>RESPONSE 1 – 2</p> <p>While it has always been the practice of the Center to maintain all medical records for a minimum of 7 years, the following changes were made to reflect that practice and become compliant with this regulation:</p> <ol style="list-style-type: none"> Policy MR 01 "Documentation: Charting & Charts" was revised to include the following verbiage: "The medical record will be maintained by the facility, in the facility or in approved storage, for at least seven years." Policy MR 07 "Retrieval of Medical Records" was revised to include the following verbiage: "Medical records will be maintained for a minimum of seven years after service." <p>These policy changes were approved by the Medical Executive Committee and the Governing Body on 2-27-12. Staff members were educated regarding the policy change and the policy was implemented on 3-1-12.</p>		

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S0624	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(7)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based upon document review and interview, the center lacked a provision for releasing medical records to authorized individuals in accordance with federal and state laws.</p> <p>Findings: 1. The policy/procedure Confidentiality of Patient Information (approved 1-12) failed to indicate that the center must release medical records upon receipt of a properly executed subpoena or court order.</p>	S0624	<p>Tag S 624 410 IAC 15-2.5-3(c) (7) Medical Records, Storage, & Admin "This RULE is not met as evidenced by: Based upon document review and interview, the center lacked a provision for releasing medical records to authorized individuals in accordance with federal and state laws." FINDINGS #1 "The policy/procedure Confidentiality of Patient Information (approved 1-12) failed to indicate that the center must release medical records upon receipt of a properly executed subpoena or court order." FINDINGS #2 "During an interview on 2-01-12 at 1145</p>	03/01/2012	

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	2. During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the policy/procedure lacked the indicated provision.		<i>hours, staff A1 confirmed that the policy/procedure lacked the indicated provision.</i> RESPONSE 1 – 2 Policy MR 02 "Guidelines for Maintaining the Medical Record as a Medical-legal Document" was revised to include the following verbiage: "All medical records are the property of Inverness Surgery Center and may not be taken away without court order, subpoena, or statute." This policy change was approved by the Medical Executive Committee and the Governing Body on 2-27-12. Staff members were educated regarding the policy change and the policy was implemented on 3-1-12.		

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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 policy and procedure review, medical staff rules and regulations review, patient medical record review, and staff interview, the facility failed to ensure records were legible in 9 of 16 charts (N2, N4, N5, N7, N8, N11, N12, N13 and N14) and failed to ensure a complete medical record for 12 of 16 charts (N2, N3, N4, N5, N6, N7, N11, N12, N13, N14, N15 and N16) and lacked a policy/procedure ensuring that all entries in the medical record (MR) were legible.</p> <p>Findings:</p> <p>1. at 2:35 PM on 2/1/12, review of the policy and procedure "Guidelines for Maintaining the Medical Record as a Medical-legal Document", indicated:</p> <p>a. under "Procedure", it reads: "...G. All blanks should be completed on special forms: special reference is made to consent forms."</p> <p>2. at 2:25 PM on 2/1/12, review of the Medical Staff Rules and Regulations,</p>	S0640	<p>Tag S 640 410 IAC 15-2.5-3(e) (1) Medical Records, Storage, & Admin</p> <p>"This RULE is not met as evidenced by: Based on policy and procedure review, medical staff rules and regulations review, patient medical record review, and staff interview, the facility failed to ensure records were legible in 9 of 16 charts N2, N4, N5, N7, N8, N11, N12, N13 and N14) and failed to ensure a complete medical record for 12 of 16 charts (N2, N3, N4, N5, N6, N7, N11, N12, N13, N14, N15 and N16) and lacked a policy/procedure ensuring that all entries in the medical record (MR) were legible."</p> <p>FINDINGS #1 "At 2:35 PM on 2/1/12, review of the policy and procedure "Guidelines for Maintaining the Medical Record as a Medical-legal Document", indicated: a. under "Procedure", it reads: "...G. All blanks should be completed on special forms: special reference is made to consent forms."</p>	03/01/2012			

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	<p>approved by the medical staff 9/28/09 and by the governing board on 10/24/09, indicated:</p> <p>a. in item "VIII.", it reads: "The attending physician shall be responsible for the preparation of a complete and legible medical record for each patient he/she admits..."</p> <p>3. review of patient medical records through out the survey process of 1/30/12 to 2/1/12, indicated:</p> <p>a. pt. N2:</p> <p>A. lacked completion on the "Anesthesia Record" form in the "Anesth Hx:", and "Medications:" area in the "Preoperative Evaluation" section of the form, and lacked documentation of "Reassessment in OR prior to induction with: Status Changed/Unchanged" not noted by the anesthesiologist</p> <p>B. had illegibility in the lower section of the " Recovery Room Record " form in the section "Patient Assessment Parameters" (in section 11. "Physician Visited")</p> <p>b. pt. N3 lacked completion by nursing staff of the times pre procedure medications (Kefzol, Zantac, Reglan, and Versed) were given (on the "Pre-Op Record"form) and lacked documentation by the anesthesiologist on the "Anesthesia Record" form in the areas: "Anesthesia Plan Proposed: General/MAC (monitored</p>		<p>FINDINGS #2</p> <p>"at 2:25 PM on 2/1/12, review of the Medical Staff Rules and Regulations, approved by the medical staff 9/28/09 and by the governing board on 10/24/09, indicated:</p> <p>a. in item "VIII.", it reads: "The attending physician shall be responsible for the preparation of a complete and legible medical record for each patient he/she admits..."During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the policy/procedure lacked the indicated provision."</p> <p>FINDINGS #3</p> <p>"Review of patient medical records throughout the survey process of 1/30/12 to 2/1/12, indicated:</p> <p>a. pt. N2: A. lacked completion on the "Anesthesia Record" form in the "Anesth Hx:", and "Medications" area in the "Preoperative Evaluation" section of the form, and lacked documentation of "Reassessment in OR prior to induction with: Status Changed/Unchanged" not noted by the anesthesiologist. B. had illegibility in the lower section of the "Recovery Room Record" form in the section "Patient Assessment Parameters" (in section 11. "Physician Visited")</p> <p>b. pt. N3 lacked completion by nursing staff of the times pre</p>				

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	<p>anesthesia care)/Regional"; "Airway Class: 1, 2, 3, or 4"; "Time" of pre op medications given; and "Anesthesia Complications: Yes/No" (in the " Post Operative Evaluation " section)</p> <p>c. pt. N4: A. lacked notation on the "Anesthesia Record" form in the areas: "Gas Off:", Post Op "SPO2, HR, B/P, RR " ; and "Anesthesia Complications: Yes/No" (in the " Post Operative Evaluation " section)</p> <p>B. had illegibility on the "Recovery Room Record" form in three areas: Oxygen "Time On"; notes in the "1130, 1135 and 1145" areas (top of the page); and in the "Patient Assessment Parameters" section in the 8. "Nausea" and 9. " Pain Intensity..." areas</p> <p>d. pt. N5: A. lacked completion by the anesthesiologist on the " Anesthesia Record " form in the " Extubated: OR/PACU " area of the " Postoperative Anesthesia Note " section</p> <p>B. was illegible on the " Recovery Room Record " form in the " SAO2 " area at " 1340 " and " 1345 " ; the amount of " LR (Lactated Ringgers) " intravenous solution administered; and in the " Patient Assessment Parameters " section " 12. Significant Other Visited " area</p> <p>e. pt. N6 lacked completion by the</p>		<p><i>procedure medications (Kefzol, Zantac, Reglan, and Versed) were given (on the "Pre-Op Record" form) and lacked documentation by the anesthesiologist on the "Anesthesia Record" form in the areas: "Anesthesia Plan Proposed: General/MAC (monitored anesthesia care)/Regional"; "Airway Class: 1, 2, 3, or 4"; "Time" of pre op medications given; and "Anesthesia Complications: Yes/No" (in the "Post-Operative Evaluation" section)</i></p> <p><i>c. pt. N4: A. lacked notation on the "Anesthesia Record" form in the areas: "Gas Off" "Post Op "SPO2, HR, B/P, RR"; and "Anesthesia Complications: Yes/No" (in the "Post-Operative Evaluation" section) B. had illegibility on the "Recovery Room Record" form in three areas: Oxygen "Time On"; notes in the "1130, 1135 and 1145" areas (top of the page); and in the "Patient Assessment Parameters" section in the 8. "Nausea"and 9. "Pain Intensity..." areas</i></p> <p><i>d. pt. N5: A. lacked completion by the anesthesiologist on the "Anesthesia Record" form in the "Extubated: OR/PACU" area of the "Postoperative Anesthesia Note" section B. was illegible on the "Recovery Room Record" form in the "SAO2" area at "1340" and "1345" ; the amount of "LR (Lactated Ringers) "intravenous</i></p>				

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	<p>anesthesiologist on the " Anesthesia Record " form in the " Gas On: " and " Gas Off " section; in the " Anesthesia End " time section; and in the " Extubated: OR/PACU " section of the " Post Operative Anesthesia Note " section f. pt. N7:</p> <p>A. lacked completion by admission and/or nursing staff on the " Authorization to Treat " form in the Advance Directive section where staff checked that the patient did have an Advance directive, but failed to note if the copy was " obtained " or " no copy provided "</p> <p>B. lacked completion on the " Anesthesia Record " form in the " Gas Off: " section and in failing to mark the box for " Monitors/Equipment--Pre-op Equip checked... "</p> <p>C. had illegibility in several areas of the " Recovery Room Record " form in the section just above " Patient Assessment Parameters "</p> <p>g. pt. N8 had a write over with the first time noted with vital signs at the top of the page</p> <p>h. pt. N11:</p> <p>A. lacked completion by the anesthesiologist of the pre op antibiotic and the time it was given and in the area of " Gas Off "</p> <p>B. had illegibility on the " Recovery Room Record " form with the next to last</p>		<p><i>solution administered; and in the "Patient Assessment Parameters" section " 12. Significant Other Visited" area</i></p> <p><i>e. pt. N6 lacked completion by the anesthesiologist on the "Anesthesia Record" form in the "Gas On" and "Gas Off" section; in the "Anesthesia End" time section; and in the "Extubated: OR/PACU" section of the "Post-Operative Anesthesia Note" section</i></p> <p><i>f. pt. N7: A. lacked completion by admission and/or nursing staff on the "Authorization to Treat" form in the Advance Directive section where staff checked that the patient did have an Advance directive, but failed to note if the copy was "obtained" or "no copy provided". B. lacked completion on the "Anesthesia Record" form in the "Gas Off" section and in failing to mark the box for "Monitors/Equipment--Pre-op Equip checked."</i></p> <p><i>C. had illegibility in several areas of the "Recovery Room Record" form in the section just above "Patient Assessment Parameters"</i></p> <p><i>g. pt. N8 had a write over with the first time noted with vital signs at the top of the page</i></p> <p><i>h. pt. N11: A. lacked completion by the anesthesiologist of the pre op antibiotic and the time it was given and in the area of "Gas Off" B. had illegibility on the "Recovery Room Record" form with the next to last time of vital signs</i></p>				

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	<p>time of vital signs documented (write over), in writing KO (keep open) for the IV (intravenous) amount (write over), and on the " Pre-Op Record " form in the area " Any loose or capped teeth? " (write overs noted)</p> <p>i. pt. N12:</p> <p>A. lacked documentation by the anesthesiologist in the " Gas Off: " section and in the " Post Operative Anesthesia Note " section in the area: " Extubated: OR/PACU "</p> <p>B. was illegible with a write over in the 8th notation of vital signs on the " Recovery Room Record " form; with a write over of medication given pre operatively on the " Pre-Op Record " form; and in the time of physician authentication on the " Consent... " form</p> <p>j. pt. N13:</p> <p>A. anesthesia failed to complete the " Anesthesia Record " form in the areas of: " Antibiotic " given pre operatively; " Reassessment in OR Prior to Induction: Status Changed or Unchanged " ; and in the " Post Operative Anesthesia Note " section for " Extubated: OR/PACU "</p> <p>B. had illegibility in the " Patient Assessment Parameters " section of the " Recovery Room Record " form in several areas of write overs</p> <p>k. pt. N14:</p> <p>A. lacked documentation by anesthesia in the " Reassessment in OR Prior to</p>		<p><i>documented (write over), in writing KO (keep open) for the IV (intravenous) amount (write over), and on the "Pre-Op Record" form in the area "Any loose or capped teeth?" (write overs noted)</i></p> <p><i>i. pt. N12: A. lacked documentation by the anesthesiologist in the "Gas Off" section and in the "Post-Operative Anesthesia Note" section in the area: "Extubated: OR/PACU" B. was illegible with a write over in the 8 th notation of vital signs on the "Recovery Room Record" form; with a write over of medication given pre operatively on the "Pre-Op Record" form; and in the time of physician authentication on the "Consent.." form</i></p> <p><i>j. pt. N13: A. anesthesia failed to complete the "Anesthesia Record" form in the areas of: "Antibiotic" given pre operatively; "Reassessment in OR Prior to Induction: Status Changed or Unchanged" ; and in the "Post-Operative Anesthesia Note "section for" Extubated: OR/PACU" B. had illegibility in the "Patient Assessment Parameters" section of the "Recovery Room Record" form in several areas of write overs</i></p> <p><i>k. pt. N14: A. lacked documentation by anesthesia in the "Reassessment in OR Prior to</i></p>				

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	<p>Induction: Status Changed/Unchanged " on the " Anesthesia Record " form</p> <p>B. had write overs on pages 16 and 17 of the " 23 Hour Patient Assessment Record " form and write overs in the section of " Gas On: " and " Anesthesia Start " time on the " Anesthesia Record " form</p> <p>1. pts. N15 and N16 lacked documentation by anesthesia of the " Gas Off " time on the " Anesthesia Record " form</p> <p>4. interview with staff member NB at 3:30 PM on 2/1/12 indicated:</p> <p>a. documentation is lacking, mainly on the " Anesthesia Record " forms and illegibility is noted, mainly on the " Recovery Room Record " form for charts N1 through N16 as listed in 3. above</p> <p>b. there is no specific facility policy related to completeness of the medical record or legibility of the medical record</p> <p>5. On 1-30-12 at 1015 hours, staff A1 was requested to provide a policy/procedure for verifying entries of questionable legibility and none was provided prior to exit.</p> <p>6. On 2-01-12 at 1145 hours, staff A1 confirmed that the MR policies lacked a provision for verifying illegible</p>		<p><i>write overs on pages 16 and 17 of the "23 Hour Patient Assessment Record" form and write overs in the section of "Gas On" and "Anesthesia Start" time on the "Anesthesia Record" form</i></p> <p><i>1. pts. N15 and N16 lacked documentation by anesthesia of the "Gas Off" time on the "Anesthesia Record" form</i></p> <p>FINDINGS #4 <i>"interview with staff member NB at 3:30 PM on 2/1/12 indicated: a. documentation is lacking, mainly on the "Anesthesia Record" forms and illegibility is noted, mainly on the "Recovery Room Record" form for charts N1 through N16 as listed in 3.above b. there is no specific facility policy related to completeness of the medical record or legibility of the medical record"</i></p> <p>FINDINGS #5 <i>"On 1-30-12 at 1015 hours, staff A1 was requested to provide a policy/procedure for verifying entries of questionable legibility and none was provided prior to exit."</i></p> <p>FINDINGS #6 <i>"On 2-01-12 at 1145 hours, staff A1 confirmed that the MR policies lacked a provision for verifying illegible information in the patient record."</i></p> <p>RESPONSE 1 – 2</p>				

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	information in the patient record.		<p>The following policies were revised to direct and clarify the proper techniques to ensure all medical records are complete, accurate, and legible at Inverness Surgery Center.</p> <p>MR 01 Documentation: Charting and Charts MR 02 Guidelines for Maintaining the Medical Record as a Medical-legal Document MR 05 Physician's Verbal and/or Telephone Orders MR 07 Retrieval of Medical Records MR 09 Completeness and Legibility of the Medical Record</p> <p>The facility policies MR 01 – Documentation: Carting and Charts, MR 02 Guidelines for Maintaining the Medical Record, and ADM 06 – Confidentiality of the Medical Record were rewritten and a new policy created MR 09 – Completeness and Legibility of the Medical Record by the Director on 02/17/12 to specify that all chart forms, including consents, pre-op, post-op, intra-op, and anesthesia records must be completed, with all indicated spaces filled in, with concise and legible documentation by the physician and nursing. The director and medical director presented the updates and new policy to the</p>		

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			<p>Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board approved the revisions. The physicians and anesthesia staff were notified by the Medical Director that per the policies MR 01, MR 02, MR 09, and ADM 06, and the facility Medical Staff Rules, <u>each</u> physician is responsible for and must legibly complete all information and fill all blanks on facility medical records pertaining to their area of service, effective 03/01/12.</p> <p>The facility director re-educated the nursing staff regarding the necessity for completeness and legibility of charting in the medical record. Staff members were reminded to chart concisely per the policy and to avoid "write-overs" in the medical record. Each staff member reviewed the new and revised policy and signed a roster confirming their understanding of the need for complete and legible documentation. The post-operative nursing staff (RN) and medical records clerk will monitor 100% of the medical records, and document exceptions to the policy on the green chart log included with each chart. The facility director posted signage in the patient care and employee areas of the facility, reminded physicians and staff to complete each medical record legibly and in its entirety. Monitoring Compliance</p>	

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			<p>The director or designee will sample random medical records each month and conduct a review for chart completeness and legibility. Mary Kay Sterrett, the facility third-party medical records review consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records meeting.</p> <p>Policy MR 02 "Guidelines for Maintaining the Medical Record as a Medical-legal Document" was revised to include the following verbiage: "All medical records are the property of Inverness Surgery Center and may not be taken away without court order, subpoena, or statute."</p> <p>This policy change was approved by the Medical Executive Committee and the Governing Body on 2-27-12. Staff members were educated regarding the policy change and the policy was implemented on 3-1-12.</p>		

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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 document review and interview, the center lacked a policy/procedure specifying which individuals, staff members and medical professionals are permitted to make entries in the medical record (MR).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating which individuals are authorized to make entries in the MR and none was provided prior to exit. The policy/procedure Guidelines for Maintaining the Medical Record as a Medical-legal Document (approved 1-12) failed to indicate what individuals were authorized to make entries in the MR. During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the policy/procedure lacked a provision ensuring that only specified health care providers and medical professionals were 	S0644	<p>Tag S 644 410 IAC 15-2.5-3(e) (2) Medical Records, Storage, & Admin</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center lacked a policy/procedure specifying which individuals, staff members and medical professionals are permitted to make entries in the medical record (MR)."</i></p> <p>FINDINGS #1 <i>"On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating which individuals are authorized to make entries in the MR and none was provided prior to exit."</i></p> <p>FINDINGS #2 <i>"The policy/procedure Guidelines for Maintaining the Medical Record as a Medical-legal Document (approved 1-12) failed to indicate what individuals were authorized to make entries in the MR."</i></p>	03/01/2012	

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	authorized to make MR entries.		<p>FINDINGS #3 <i>"During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the policy/procedure lacked a provision ensuring that only specified health care providers and medical professionals were authorized to make MR entries."</i></p> <p>RESPONSE 1 – 2 The following policies were revised to direct and clarify the proper techniques to ensure all medical records are complete, accurate, and legible at Inverness Surgery Center. MR 01 "Documentation: Charting and Charts" – speaks to which medical professional will typically be completing various parts of the medical record. MR 02 "Guidelines for Maintaining the Medical Record as a Medical-legal Document" includes the following verbiage: "Only persons involved in the direct care of the patient are authorized to chart entries in the medical record." MR 09 "Completeness and Legibility of the Medical Record" includes the following verbiage: "Each blank and space for documentation must be completed by the appropriate professional." The director and medical director presented the updates and new policy to the Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board</p>		

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NAME OF PROVIDER OR SUPPLIER INVERNESS SURGERY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 8004 CARNEGIE BOULEVARD FORT WAYNE, IN 46804		
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			<p>approved the revisions. The physicians and anesthesia staff were notified by the Medical Director that per the policies MR 01, MR 02, MR 09, and ADM 06, and the facility Medical Staff Rules, <u>each</u> physician is responsible for and must legibly complete all information and fill all blanks on facility medical records pertaining to their area of service, effective 03/01/12.</p> <p>Staff members were educated on the policy revisions effective 3-1-12.</p> <p>Monitoring Compliance The director or designee will sample random medical records each month and conduct a review for chart completeness and legibility. Mary Kay Sterrett, the contracted certified medical records reviewer consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records meeting.</p>		

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S0646	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(3)</p> <p>All entries in the medical record must be as follows:</p> <p>(3) Authenticated and dated in accordance with section 4(b)(3)(N) of this rule.</p> <p>Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure that standing orders were authenticated within 30 days of discharge for 8 of 16 patients (N1, N3, N6, N11, N12, N14, N15 and N16), and failed to follow facility policy for authentication of verbal and telephone orders for 4 of 16 patients (N4, N11, N13 and N15).</p> <p>Findings:</p> <p>1. at 2:25 PM on 2/1/12, review of the Medical Staff Rules and Regulations, approved by the medical staff 9/28/09, and by the governing board on 10/24/09, indicated:</p> <p>a. in item "XIX.", it reads: "Due to the simplicity of the record, the Surgery Center personnel shall notify the physician whose chart is not complete in fourteen (14) working days following discharge of the patient...If records remaining incomplete at the end of the thirty (30) days following discharge, the</p>	S0646	<p>Tag S 646 410 IAC 15-2.5-3(e) (3) Medical Records, Storage, & Admin "This RULE is not met as evidenced by: Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure that standing orders were authenticated within 30 days of discharge for 8 of 16 patients (N1, N3, N6, N11, N12, N14, N15 and N16), and failed to follow facility policy for authentication of verbal and telephone orders for 4 of 16 patients (N4, N11, N13 and N15)." FINDINGS #1 "at 2:25 PM on 2/1/12, review of the Medical Staff Rules and Regulations, approved by the medical staff 9/28/09, and by the governing board on 10/24/09, indicated: a. in item "XIX.", it reads: "Due to the simplicity of the record, the Surgery Center personnel shall notify the physician whose chart is not complete in fourteen (14) working days following discharge of the patient...If records remaining incomplete at the end of the thirty (30) days following discharge, the Medical Director</p>	03/01/2012			

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	<p>Medical Director will be notified and disciplinary action will be at his/her discretion..."</p> <p>2. at 11:20 AM on 2/1/12, review of the policy and procedure "Physician's Verbal and/or Telephone Orders", MR 05, indicated: a. under "Procedure", it reads: "...C. The physician should sign pre-operative verbal and telephone orders on the day of the patient's procedure. D. Post-operative verbal and telephone orders should be signed prior to the physician leaving the facility or within 24 hours when possible."</p> <p>3. at 2:35 PM on 2/1/12, review of the policy and procedure "Guidelines for Maintaining the Medical Record as a Medical-legal Document", MR 02, indicated: a. under "Procedure", it reads: "A. The medical record is maintained as a unit record. All entries in the medical record must be authenticated (name and professional status) and dated..."</p> <p>4. review of patient medical records through out the survey process of 1/30/12 to 2/1/12, indicated: a. pt. N1 had 2 pages of standing orders faxed from the physician's office on 5/7/10 that lack a date of authentication</p>		<p><i>will be notified and disciplinary action will be at his/her discretion..." FINDINGS #2 "At 11:20 AM on 2/1/12, review of the policy and procedure "Physician's Verbal and/or Telephone Orders", MR 05, indicated: a. under "Procedure", it reads: "...C. The physician should sign pre-operative verbal and telephone orders on the day of the patient's procedure. D. Post-operative verbal and telephone orders should be signed prior to the physician leaving the facility or within 24 hours when possible." FINDINGS #3 "At 2:35 PM on 2/1/12, review of the policy and procedure "Guidelines for Maintaining the Medical Record as a Medical-legal Document", MR 02, indicated: a. under "Procedure", it reads: "A. The medical record is maintained as a unit record. All entries in the medical record must be authenticated (name and professional status) and dated..." FINDINGS #4 "review of patient medical records through out the survey process of 1/30/12 to 2/1/12, indicated: a. pt. N1 had 2 pages of standing orders faxed from the physician's office on 5/7/10 that lack a date of authentication for the day of surgery, 6/17/10 (authenticated, but not dated) b. pt. N3 had faxed orders from the physician's office that were faxed on 10/26/10 but were not authenticated on the day</i></p>				

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	<p>for the day of surgery, 6/17/10 (authenticated, but not dated)</p> <p>b. pt. N3 had faxed orders from the physician's office that were faxed on 10/26/10 but were not authenticated on the day of surgery (11/4/10) or within 30 days of service</p> <p>c. pt. N4 had 6 different verbal and telephone orders on 11/22/10 that were not authenticated until 12/5/10</p> <p>d. pt. N6 had faxed orders from the physician's office dated 10/5/11 that were not authenticated on the day of service, 12/2/11 (electronic signature from the office was 10/5/11)</p> <p>e. pt. N11 had:</p> <p>A. faxed orders from the physician's office dated 11/24/10 that were not authenticated on the day of service, 1/13/11 (electronic signature from the office was 11/24/10)</p> <p>B. telephone orders (2) on 1/13/11 that lacked authentication by the physician</p> <p>f. pt. N12 had faxed orders from the physician's office dated 1/17/11 that were not authenticated on the day of service, 1/27/11 (electronic signature from the office was 1/17/11)</p> <p>g. pt. N13 had:</p> <p>A. a telephone order on 2/3/11 that was authenticated, but not dated, making it unclear if signed within 24 hours</p> <p>B. standing orders faxed from the physician's office on 1/5/11 that were</p>		<p><i>of surgery (11/4/10) or within 30 days of service c. pt. N4 had 6 different verbal and telephone orders on 11/22/10 that were not authenticated until 12/5/10 d. pt. N6 had faxed orders from the physician's office dated 10/5/11 that were not authenticated on the day of service, 12/2/11 (electronic signature from the office was 10/5/11) e. pt. N11 had: A. faxed orders from the physician's office dated 11/24/10 that were not authenticated on the day of service, 1/13/11 (electronic signature from the office was 11/24/10) B. telephone orders (2) on 1/13/11 that lacked authentication by the physician f. pt. N12 had faxed orders from the physician's office dated 1/17/11 that were not authenticated on the day of service, 1/27/11 (electronic signature from the office was 1/17/11) g. pt. N13 had: A. a telephone order on 2/3/11 that was authenticated, but not dated, making it unclear if signed within 24 hours B. standing orders faxed from the physician's office on 1/5/11 that were</i></p>				

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	<p>authenticated, but not dated, on the date of service 2/3/11</p> <p>h. pt. N14 had faxed orders from the physician's office dated 1/5/11 that were authenticated, but not dated, making it unclear if signed on the day of service, 1/27/11 (electronic signature from the office was 1/5/11)</p> <p>i. pt. N15 had:</p> <p>A. faxed orders from the physician's office dated 8/31/11 that were not authenticated and dated on the day of surgery, 12/22/11</p> <p>B. verbal orders of 12/22/11 that were authenticated, but not dated, making it unclear that authentication took place within 24 hours of the order</p> <p>j. pt. N16 had faxed orders from the physician's office dated 12/19/11 that were authenticated electronically on 1/14/12 (date of service was 12/28/11)</p> <p>5. Interview with staff member NB at 3:30 PM on 2/1/12, indicated:</p> <p>a. faxed standing physician orders are either not authenticated and dated on the date of service, or have authentication, but no date, as required by policy, as noted in 4. above</p> <p>b. verbal and telephone orders are either not authenticated within 24 hours, as required by policy, or not dated, making it unclear if they were signed with that time frame, and not per facility policy</p>		<p><i>orders from the physician's office dated 8/31/11 that were not authenticated and dated on the day of surgery, 12/22/11 B. verbal orders of 12/22/11 that were authenticated, but not dated, making it unclear that authentication took place within 24 hours of the order j. pt. N16 had faxed orders from the physician's office dated 12/19/11 that were authenticated electronically on 1/14/12 (date of service was 12/28/11)"</i></p> <p><i>FINDINGS #5 "Interview with staff member NB at 3:30 PM on 2/1/12, indicated: a. faxed standing physician orders are either not authenticated and dated on the date of service, or have authentication, but no date, as required by policy, as noted in 4. above b. verbal and telephone orders are either not authenticated within 24 hours, as required by policy, or not dated, making it unclear if they were signed with that time frame, and not per facility policy requiring a date with entries made in the medical record c. the standing order policy does not address the expectation of authentication of orders d. the medical staff rules and regulations do not address expectations of authentication of standing orders or verbal/telephone orders"</i></p> <p><i>RESPONSE 1 – 5 The following policies were revised to direct and clarify the proper techniques to ensure all medical records are</i></p>				

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	<p>requiring a date with entries made in the medical record</p> <p>c. the standing order policy does not address the expectation of authentication of orders</p> <p>d. the medical staff rules and regulations do not address expectations of authentication of standing orders or verbal/telephone orders</p>		<p>complete, accurate, and legible and properly authenticated at Inverness Surgery Center. MR 01 "Documentation: Charting and Charts" – includes the following verbiage: "All H & P's, physician order sheets, consents, dictation sheets, Operative, and Post-procedure reports must include the physician's signature, the date, and time the document is signed." MR 05 "Physician's Verbal and/or Telephone Orders" directs the proper technique for documentation of these orders. It also includes the following verbiage: "The physician should sign pre-operative verbal and telephone orders on the day of the patient's procedure" and "Post-operative verbal and telephone orders should be signed, timed and dated prior to the physician leaving the facility or within 24 hours. The director and medical director presented the updates and new policy to the Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board approved the revisions. The physicians and anesthesia staff were notified by the Medical Director that per the policies MR 01, MR 02, MR 09, and ADM 06, and the facility Medical Staff Rules, <u>each</u> physician is responsible for and must legibly complete all information and fill all blanks on facility medical records pertaining to their area of service, effective 03/01/12. Staff members were</p>		

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			educated on the policy revisions effective 3-1-12. Monitoring Compliance The director or designee will sample random medical records each month and conduct a review for chart completeness and legibility. Mary Kay Sterrett, the contracted certified medical records reviewer consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records meeting.	

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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 upon document review and interview, the center failed to ensure that verbal order authentication in the medical record (MR) was performed in compliance with center policy.</p> <p>Findings:</p> <p>1. The policy/procedure Physician 's Verbal and/or Telephone Orders (approved 1-12) failed to indicate the requirement to date and time the entry when the order was authenticated to validate compliance in completing the medical record within 24 hours per center policy and within 30 days per State law.</p> <p>2. During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the</p>	S0780	<p>Tag S 780 410 IAC 15-2.5-4(b)(3)(N) MEDICAL STAFF; ANESTHESIA AND SURGICAL</p> <p><i>"This RULE is not met as evidenced by: Based upon document review and interview, the center failed to ensure that verbal order authentication in the medical record (MR) was performed in compliance with center policy."</i></p> <p>FINDINGS #1 <i>"The policy/procedure Physician 's Verbal and/or Telephone Orders (approved 1-12) failed to indicate the requirement to date and time the entry when the order was authenticated to validate compliance in completing the medical record within 24 hours per center policy and within 30</i></p>	03/01/2012	

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	policy/procedure lacked the indicated provisions to validate compliance.		<p><i>days per State law."</i></p> <p>FINDINGS #2 <i>"During an interview on 2-01-12 at 1145 hours, staff A1 confirmed that the policy/procedure lacked the indicated provisions to validate compliance."</i></p> <p>RESPONSE 1 – The following policy was revised to direct and clarify the proper techniques to ensure all medical records are complete, accurate, and legible and properly authenticated at Inverness Surgery Center. MR 05 "Physician's Verbal and/or Telephone Orders" includes the following verbiage: "Post-operative verbal and telephone orders will be signed, timed and dated prior to the physician leaving the facility or within 24 hours." and "All orders and medical records will be complete within 30 days to maintain compliance with Indiana State Department of Health regulations. Any medical record that is not in compliance will be reported through the Quality Improvement Committee to the Medical Executive Committee and Governing Body." The director and medical director presented the policy revisions to the Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board approved the revisions. The physicians and</p>		

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			<p>anesthesia staff were notified by the Medical Director of the policy revisions and the facility Medical Staff Rules reinforce that <u>each</u> physician is responsible for and must legibly complete all information and fill all blanks on facility medical records pertaining to their area of service, effective 03/01/12.</p> <p>Staff members were educated on the policy revisions effective 3-1-12.</p> <p>Monitoring Compliance The director or designee will sample random medical records each month and conduct a review for chart completeness and legibility. Mary Kay Sterrett, the contracted certified medical records reviewer consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records meeting.</p>	

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S0840	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(c)(2)</p> <p>(c) The anesthesia service is responsible for all anesthesia administered in the center as follows:</p> <p>(2) A requirement that anesthesia equipment must be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.</p> <p>Based on document review and interview, the center failed to ensure that all anesthesia equipment was checked for operational readiness and safety before each administration with a patient.</p> <p>Findings:</p> <p>1. The policy/procedure Pre-Induction Equipment (approved 1-12)) indicated the following: "All anesthesia machines will undergo a pre-induction check prior to the first case of the day." The policy/procedure failed to require an equipment check prior to use with each patient.</p> <p>2. During an interview on 2-01-12 at</p>	S0840	<p>Tag S 840 410 IAC 15-2.5-4(c) (2) MEDICAL STAFF; ANESTHESIA AND SURGICAL</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to ensure that all anesthesia equipment was checked for operational readiness and safety before each administration with a patient."</i></p> <p>FINDINGS #1 <i>"The policy/procedure Pre-Induction Equipment (approved 1-12)) indicated the following: "All anesthesia machines will undergo a pre-induction check prior to the first case of the day." The policy/procedure failed to require an equipment check prior to use with each patient."</i></p> <p>FINDINGS #2</p>	03/01/2012	

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	0915 hours, staff A1 confirmed that the policy/procedure lacked the required provision.		<p><i>"During an interview on 2-01-12 at 0915 hours, staff A1 confirmed that the policy/procedure lacked the required provision."</i></p> <p>RESPONSE 1 – Policy AN 04 "Pre-Induction Equipment Check" documents the practice of the Center to perform a pre-induction check of each anesthesia machine according to the manufacturer's recommendation prior to the first case of the day. Each patient's anesthesia record documents that the anesthesiologist checks medication and machinery prior to each case. The following verbiage: "The anesthesiologist will check for the availability of appropriate medications and will check the anesthesia equipment for operational readiness and safety prior to use on each patient and document that equipment check on the anesthesia record" was added to Policy AN 04 to match the current practice and ensure compliance with the regulation. The director and medical director presented the policy revisions to the Medical Executive Committee (MEC) and Board on 2/27/12. The MEC and Board approved the revisions. The physicians and anesthesia staff were notified by the Medical Director of the policy revisions, effective 03/01/12. Staff members were educated on</p>	

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			the policy revisions effective 3-1-12.	

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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, medical staff rules and regulations review, patient medical record review, and staff interview, the medical staff failed to ensure the implementation of facility policy and rules and regulations related to history and physical preparations prior to surgery for 3 of 16 patients (N4, N8 and N9).</p> <p>Findings: 1. at 2:25 PM on 2/1/12, review of the</p>	S0860	<p>Tag S 860 410 IAC 15-2.5-4(d)(2)(B) MEDICAL STAFF; ANESTHESIA AND SURGICAL</p> <p><i>"This RULE is not met as evidenced by: Based on policy and procedure review, medical staff rules and regulations review, patient medical record review, and staff interview, the medical staff failed to ensure the implementation of facility policy and rules and regulations related to history and physical preparations prior to surgery for 3</i></p>	02/27/2012			

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	<p>medical staff rules and regulations, approved by the medical staff on 9/28/09, and by the governing board on 10/24/09, indicated:</p> <p>a. in item "IX.", it reads: "A pertinent history and physical examination shall be performed according to the Centers guidelines or concurrent with the admission of the patient. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed..."</p> <p>b. in item "XVII.", it reads: "All podiatry procedures shall be performed in conjunction with the regulations set by the Surgery Center and the Medical Executive Committee. An adequate history and physical shall be performed by a physician for each podiatry patient prior to surgery."</p> <p>2. at 11:55 AM on 2/1/12, review of the policy and procedure "History and Physical", MR 03, indicated:</p> <p>a. under "Procedure", it reads: "A. A medical History & Physical (H&P) will be done on each patient prior to the date of surgery or by the surgeon and/or anesthesiologist upon admission to the facility...2. H & P's done outside the facility must be performed within 30 days from the date of surgery. The surgeon must also review and indicate any</p>		<p><i>of 16 patients (N4, N8 and N9)."</i></p> <p>FINDINGS #1 "At 2:25 PM on 2/1/12, review of the medical staff rules and regulations, approved by the medical staff on 9/28/09, and by the governing board on 10/24/09, indicated:</p> <p>a. in item "IX.", it reads: "A pertinent history and physical examination shall be performed according to the Centers guidelines or concurrent with the admission of the patient. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed..."</p> <p>b. in item "XVII.", it reads: "All podiatry procedures shall be performed in conjunction with the regulations set by the Surgery Center and the Medical Executive Committee. An adequate history and physical shall be performed by a physician for each podiatry patient prior to surgery."</p> <p>FINDINGS #2 "At 11:55 AM on 2/1/12, review of the policy and procedure "History and Physical", MR 03, indicated:</p> <p>a. under "Procedure", it reads: "A. A medical History & Physical (H&P) will be done on each patient prior to the date of surgery or by the surgeon and/or anesthesiologist upon admission to the facility...2. H & P's done outside the facility must be</p>				

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	<p>changes to the patient's status or no change if applicable on the date of surgery..."</p> <p>b. under "Procedure", it reads: "B. In the case of podiatry or ophthalmology cases, the anesthesiologist will complete the H&P portion after examining the patient."</p> <p>3. review of patient medical records through out the survey process of 1/30/12 to 2/1/12 indicated:</p> <p>a. pt. N4:</p> <p>A. had a dictated H&P done on 11/21/10</p> <p>B. had surgery on 11/22/10</p> <p>C. had authentication (signature and date only) by the physician on 11/22/10 on a blank one page "History" form in the patient's chart</p> <p>D. lacked a note by the physician as to whether there were any changes to the previous day's dictated H & P prior to the patient's surgery</p> <p>b. pt. N8:</p> <p>A. lacked completion of the "Physical Examination" portion of the one page "History" form on 7/5/11 (the form was authenticated by the practitioner on 7/5/11, but lacked a physical exam--the dictated H & P in the chart was dated 2/9/11 with a fax date of 6/22/11)</p>		<p><i>performed within 30 days from the date of surgery. The surgeon must also review and indicate any changes to the patient's status or no change if applicable on the date of surgery..."</i></p> <p><i>b. under "Procedure", it reads: "B. In the case of podiatry or ophthalmology cases, the anesthesiologist will complete the H&P portion after examining the patient."</i></p> <p>FINDINGS #3</p> <p><i>"Review of patient medical records throughout the survey process of 1/30/12 to 2/1/12 indicated:</i></p> <p><i>a. pt. N4: A. had a dictated H&P done on 11/21/10 B. had surgery on 11/22/10 C. had authentication (signature and date only) by the physician on 11/22/10 on a blank one page "History" form in the patient's chart D. lacked a note by the physician as to whether there were any changes to the previous day's dictated H & P prior to the patient's surgery</i></p> <p><i>b. pt. N8: A. lacked completion of the "Physical Examination" portion of the one page "History" form on 7/5/11 (the form was authenticated by the practitioner on 7/5/11, but lacked a physical exam--the dictated H & P in the chart was dated 2/9/11 with a fax date of 6/22/11)</i></p> <p><i>c. pt. N9: A. had surgery on 8/1/11 for "Arthroplasty 2 nd toe right foot..." by a podiatrist B. had the one page H & P form</i></p>				

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	<p>c. pt. N9:</p> <p>A. had surgery on 8/1/11 for "Arthroplasty 2nd toe right foot..." by a podiatrist</p> <p>B. had the one page H & P form completed by the podiatrist on 8/1/11</p> <p>C. had a H & P form from the podiatrist's office dated 7/27/11 that had a portion at the bottom to be completed by the anesthesiologist that was blank</p> <p>4. interview with staff member NB at 3:30 PM on 2/1/12, indicated:</p> <p>a. the policy related to H & P's (MR 03), should not have the language "if applicable" if there is no change to a H&P done prior to the date of surgery, an update must be done and indicate change, or no change</p> <p>b. pt. N9 should have had a H&P done by the anesthesiologist prior to surgery, the podiatrist was not to have completed the one page H&P form prior to the patient's surgery</p>		<p><i>completed by the podiatrist on 8/1/11 C. had a H & P form from the podiatrist's office dated 7/27/11 that had a portion at the bottom to be completed by the anesthesiologist that was blank"</i></p> <p>FINDINGS #4 "Interview with staff member NB at 3:30 PM on 2/1/12, indicated: a. the policy related to H & P's (MR 03), should not have the language "if applicable" if there is no change to a H&P done prior to the date of surgery, an update must be done and indicate change, or no change b. pt. N9 should have had a H&P done by the anesthesiologist prior to surgery, the podiatrist was not to have completed the one page H&P form prior to the patient's surgery"</p> <p>RESPONSE 1 – 4 Policy MR 03 "History and Physical" was revised to remove the verbiage "if applicable" relating to the "change" or "no change" statement in the policy on 2/15/12. The policy now reads that if the H&P is done prior to the surgery date, it must be updated on the day of surgery. If no changes are required, the update is marked as such, with the phrase "no change". This revision was submitted and approved by the Medical</p>		

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			<p>Executive Committee and the Governing Body on 2-27-12. The medical director informed the physicians in the center of the necessity to comply with the policy.</p> <p>As noted in Policy MR 03 "History and Physical", it has always been the practice of the Center that "in the case of podiatry or ophthalmology cases the anesthesiologist will complete the H&P portion after examining the patient". Signage was posted in physician areas of the Center to re-emphasize the importance and expectations of compliance with this policy.</p> <p>Staff RN's were reminded of the requirement of appropriately executed H&Ps prior to taking the patient to the OR.</p> <p>Monitoring Compliance The director or designee will sample random medical records each month and conduct a review for correct use, updating, and notating on the History and Physical form. Mary Kay Sterrett, the facility third-party medical records review consultant, was informed of the new policy, the policy revision, re-education, and expectations by the director at the quarterly medical records 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, observation and interview, the center failed to ensure that required emergency equipment was available for use if needed.</p> <p>Findings:</p> <p>1. The policy/procedure Crash Cart (approved 1-12) and Crash Cart Checklist (OR)+(Pre-Post) failed to indicate where an oximeter was listed as available for use</p>	S0862	Plan of Correction 04/01/2012Tag S 862 410 IAC 15-2.5-4(d)(2)(C) MEDICAL STAFF; ANESTHESIA AND SURGICAL Requirement for surgical services include: (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: (C) A provision for the following equipment and	03/30/2012

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	<p><u>or</u> on the code cart if needed.</p> <p>2. During a tour on 1-30-12 at 1120 hours in the Pre and Post-Op area, no oximeter was observed in the immediate area of the crash cart.</p> <p>2. During an interview on 1-30-12 at 1300 hours, staff A3 confirmed that the policy/procedure lacked the required equipment.</p>		<p>supplies to be available to the surgical and recovery areas: (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>"This RULE is not met as evidenced by: Based on document review, observation and interview, the center failed to ensure that required emergency equipment was available for use if needed." FINDINGS #1 "The policy/procedure Crash Cart (approved 1-12) and Crash Cart Checklist (OR)+(Pre-Post) failed to indicate where an oximeter was listed as available for use or on the code cart if needed."</p> <p>FINDINGS #2 "During a tour on 1-30-12 at 1120 hours in the Pre and Post-Op area, no oximeter was observed in the immediate area of the crash cart.."</p> <p>FINDINGS #3 "During an interview on 1-30-12 at 1300 hours, staff A3 confirmed that the policy/procedure lacked the required equipment." Actions Taken: The oximeters are located near the Pre/Post crash cart in Pre/Post-Op bays 1 through 8, and in the 23-hour rooms, and near the OR crash cart in OR suites 1 through 4. The policies PC 087 Cardiac and/or Respiratory Arrest (Code Blue) and PC 086 ACLS Protocol were</p>		

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			<p>amended to include the reference to the locations of the mobile and stationary pulse oximetry options within the center, and to the Crash Cart Checklists for OR and Pre/Post areas. All staff were educated regarding the location of the oximetry units, and additions to the policies and checklist. See attachments: A: Policy PC 087 Cardiac and/or Respiratory Arrest (Code Blue) B: Policy PC 086 ACLS Protocol C: Inverness Surgery Center Crash Cart Checklist Attachment A:</p> <p>Title Cardiac and/or Respiratory Arrest (Code Blue) PC 087 Origination Date Effective: 9/3/2008 Authorized By Nora Bass Revised: 4/2011, 1/2012 Medical Director John Drake D. O.</p> <p>PURPOSE: To be knowledgeable in handling cardiac and/or respiratory arrest through a maximum team effort, to sustain life. POLICY: The following procedures shall be followed in the event a patient or other individual experiences cardiac or respiratory arrest in the Center. PROCEDURE: To preserve life during a life-threatening condition of cardiac and/or respiratory arrest through a maximum team effort. A Team Members 1. Any available physician to direct the code 2. Charge Nurse or ACLS</p>	

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			<p>certified RN to direct the code in the absence of a physician 3. All available staff nurses B Duties 1. First nurse to patient a. Assess patient, ABC's b. Call to summon help c. Begin CPR as approved by American Heart Association d. Assist anesthesiologist/physician with care 2. Second Nurse a. Bring crash cart and suction equipment b. Assist physician c. Takes over breathing patient with ambu bag while first nurse continues external cardiac compression unless an anesthesiologist is managing the airway. 3. Nurses trained in ACLS (ACLS Protocol located on crash cart) a. Take charge if code already in progress until physician or EMS arrives. 4. Available Staff a. Clear room for crash cart b. Place call to the patient's physician, if not in facility. c. Stands by for further instructions d. EKG/monitor is stationed at head to side of bed e. Pulse oximetry obtained if desired f. Nurse starts IV if needed g. ACLS trained responsible nurse to chart medications and time given on chart and CPR record (see attached) h. Copy the chart including medications sheet and CPR flow sheet to send with transfer. i. Obtain extra supplies equipment, drugs, and any other items needed during the Code process. 5. Secretary a. Notify staff using paging system 1) Press "All Page" button on phone</p>		

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			then announce "code blue" and location two times. b. Notify 911 c. Copy the chart in preparation for transfer when requested. 6. Physician is head of team. (If physician is absent the DON, Charge Nurse or designee will direct the team) Responsibilities: a. ECG b. CPR c. Defibrillation d. Administering medications e. Transferring physician determines and orders life support measures, which are medically appropriate to stabilize the patient prior to transfer. f. Before transfer, the transferring physician secures a receiving physician and hospital that are appropriate to the patients' medical needs and that will accept responsibility for the patients care. 7. If a code situation should occur when a physician and the ACLS trained RN are not present, only basic rescuer CPR will be performed on the patient until the emergency medical team arrives. 8. Pulse oximetry is located in each Pre and Post-Op Bay, each OR suite, and via two portable monitors located in each 23-hour patient room. C Documentation 1. Documentation is completed in the patients' progress notes. 2. If the need arises to transfer the patient it is the responsibility of the individual in charge to notify the family. 3. It is the responsibility of the Director to verify completion of all documentation regarding the		

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			<p>code as well as an Incident Report 4. Director notifies the Executive Director Attachment B: Inverness Surgery Center Policy & Procedure</p> <p>A. Title</p> <p>ACLS Protocol PC 086 Origination Date Effective: 9/3/2008 Authorized By Nora Bass Updated: 1/2012 Medical Director John Drake, D.O.</p> <p>PURPOSE: To provide a systematic approach to dealing with people experiencing a cardiopulmonary emergency or even sudden death. POLICY: Management of life threatening medical conditions will be instituted immediately upon identification of the problem using approved, American Heart Association, emergency protocols. PROCEDURE: A</p> <p>IMPLEMENTATION 1. The Medical Executive Committee (MEC) will be knowledgeable in Advanced Cardiac support Universal Algorithm for adults, infants, and children. a. The Medical Director or designee will have medical control and direct the medical care provided by any and all personnel: 1. With assistance develop plan for treatment of life threatening medical conditions. (See Cardiac and/or Respiratory Arrests Procedure). 2. Determine the qualifications and assess the</p>		

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			<p>competence of the staff involved.</p> <p>3. Responsible for the protocols that allow non-physician to function in extended roles as appropriate (e.g. to permit endotracheal intubation, defibrillation, and to administer emergency IV drugs).</p> <p>4. Standardize necessary equipment and plan its location, maintenance, and restocking.</p> <p>2. Provide on-going monitoring of the program, evaluation of and feedback of performance, and review of all records to assure the quality of care.</p> <p>B. ATTENDING PHYSICIAN RESPONSIBILITY</p> <p>1. In the event that a life threatening condition should arise with a patient, the attending surgeon and/or anesthesiologist will be available by phone and if necessary can be available on the premises. If a condition arises that are non-emergent the attending surgeon and or anesthesiologist will be available by phone. In the event that the physician can not be reached the physician on call for the attending surgeon and/or anesthesiologist will be notified.</p> <p>C. NURSING RESPONSIBILITY</p> <p>3. All individuals working as registered nurses employed at the center must have current Advanced Cardiac Life Support Certification.</p> <p>4. It is responsibility of every nurse to know:</p> <p>a. Location and use of emergency call (alert) system.</p> <p>b. Location and contents of the crash cart.</p> <p>c. How to</p>		

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			<p>operate defibrillators with assorted paddles. d. How to prepare and provide Bristojets and other medications as appropriate. e. How to prepare, provide, and apply as appropriate:</p> <p>1. IV solutions and administration sets. 2. Syringes, needles, angiocaths, and tourniquets. 3. Gloves, antiseptic solutions, dressings 4. Procedure trays 5. Monitoring devices. (1) Pulse oximetry is located in each Pre and Post-Op Bay, each OR suite, and via two portable monitors located in each 23-hour patient room. 5. Nurse Duties a. Summon help and request the crash cart. b. Assist in repositioning the patient as necessary. c. Assess breathing and begin ventilations as necessary. d. Begin restoration of circulation as necessary. e. Delegate the following responsibilities to other team members who respond (these include, but are not limited to): 1. Medication preparation 2. Defibrillator operating 3. Airway management 4. IV access x two(2) (If possible) 5. Documentation f. Control traffic-limit personnel to those necessary to implement life saving measures. 6. Scrub Tech Duties a. It is the responsibility of the scrub person to institute measures to maintain sterility of the surgical site including the back table and mayo stand. b. Assist as needed during sterile</p>	

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			<p>procedures. B DOCUMENTATION Documentation of a life-threatening emergency is accomplished on the appropriate form: (See attached) 1. Documentation shall included: a. Time of onset of emergency b. Medication given, time, amount, and route c. Defibrillation time and number of joules d. Procedures performed e. Names of personnel utilized during emergency INVERNESS SURGERY CENTER CRASH CART CHECKLIST YEAR: TOP OF CRASH CART:QUANTITYEXP DATEMONTH:NAME: Defibrillator/defub paddles/pacing pads Chest board January Pressure bag Peds ambu bag Adult ambu bag February Stethoscope Peds AED pads Adult AED pads March EKG patches x2 EKG gel KY jelly April Assorted tape/glue stick Pulse Oximeter Available in Bays 1-8, OR 1-4, 23 hr rooms May MEDICATIONS CHECK:QUANTITYEXP DATE Atropine 1ml/10ml syringe Dextrose 50% 50ml June Epinephrine 1:10,000 syringe</p>	

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			Lidocaine 2% 100ml/5ml syringe NaBicarb 8.4% 50mEg syringe July Adneosine 5ml/2ml injection Calcium chloride 1g/10ml syringe Amiodarone 150mg/3ml August Dextrose 25% syringe (peds) Lanoxin 500mcg/2ml Sodium chloride 0.9% 10ml inj September Lasix 40mg/4ml injection Narcan 0.4mg/ml Procainamide inj 1gm/2ml October Flumazenil 0.5mg/5ml injection Sodium bicarb 4.2%/5ml (peds) Verapamil 5mg/2ml inj November Epinephrine 1:1,000 30ml Vasopressin 20u/1ml Magnesium Sulfate 50% 5gm/10ml December Hydralazine 20mg/ml Diphenhydramine 50mg/ml Esmolol 100mg/10ml Phenytoin 100mg/2ml Dobutamine 250mg/20ml Ephedrine 50mg/ml Dopamine 200mg/5ml Metoprolol 5mg/5ml Phenylephrine 1% 10mg/ml Solu-Cortef 10mg		

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S1010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on document review and interview, the center failed to maintain its policy/procedures regarding pharmacy multi-dose vials in accordance with acceptable standards of practice at the facility.</p> <p>Findings:</p> <p>1. The United States Pharmacopeia (USP) General Chapter 797 [16] indicated the following for multi-dose vials of sterile pharmaceuticals: " If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. "</p> <p>2. The policy/procedures Medications, Administration of (approved 1-12)</p>	S1010	<p>Tag S 1010 410 IAC 15-2.5-6(3) (A) PHARMACEUTICAL SERVICES "This RULE is not met as evidenced by: Based on document review and interview, the center failed to maintain its policy/procedures regarding pharmacy multi-dose vials in accordance with acceptable standards of practice at the facility." FINDINGS #1 "The United States Pharmacopeia (USP) General Chapter 797 [16] indicated the following for multi-dose vials of sterile pharmaceuticals: If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. " FINDINGS #2 "The policy/procedures Medications, Administration of (approved 1-12) Medication Ordering and Distribution (approved 1-12) and</p>	03/01/2012	

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	<p>Medication Ordering and Distribution (approved 1-12) and Non-Narcotic Medications used in Anesthesia (approved 1-12) indicated a provision for use of multi-dose vials and lacked a requirement for dating a multi-dose vial when opened and discarding within 28 days or requiring the vial to be used with one patient and disposed of on the same day.</p> <p>3. During an interview on 2-01-12 at 0915 hours, staff A1 confirmed that the policy/procedures lacked a requirement to date the multi-dose vial when it was opened and lacked a requirement to discard the opened vial within 28 days or less.</p>		<p><i>Non-Narcotic Medications used in Anesthesia (approved 1-12) indicated a provision for use of multi-dose vials and lacked a requirement for dating a multi-dose vial when opened and discarding within 28 days or requiring the vial to be used with one patient and disposed of on the same day."</i> FINDINGS #3 <i>"During an interview on 2-01-12 at 0915 hours, staff A1 confirmed that the policy/procedures lacked a requirement to date the multi-dose vial when it was opened and lacked a requirement to discard the opened vial within 28 days or less. RESPONSE 1 - 3 It is the practice of the Center to use multiple dose vials only when absolutely necessary. It has been the practice of the Center to discard multiple use vials within 28 days from opening. The following verbiage was added to Policy PC 102 "Medications, Administration of": "Medications supplied in opened multiple dose vials expire when manufacturer's expiration date is met or in 28 days, whichever occurs first." to match the current practice of the Center and document compliance with the regulation. The policy change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. All staff members were educated on the policy change by 3-1-12.</i></p>		

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S1020	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(D)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(D) Reporting of adverse reactions and medication errors to the practitioner responsible for the patient and the appropriate committee, and documented in the patient's record.</p> <p>Based on document review and interview, the center failed to have a policy/procedure ensuring medication errors would be documented in the patient record.</p> <p>Findings:</p> <p>1. The policy/procedures Medication Errors (approved 1-12) and Non-Narcotic Medications used in Anesthesia (approved 1-12) failed to indicate that a medication error will be documented <u>in the patient record</u> when the medication was administered or omitted in error.</p> <p>3. During an interview on 01-31-12 at 1105 hours, staff A1 confirmed that the policy/procedures lacked the requirement.</p>	S1020	<p>Tag S 1020410 IAC 15-2.5-6(3) (D) PHARMACEUTICAL SERVICES</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to have a policy/procedure ensuring medication errors would be documented in the patient record."</i></p> <p>FINDINGS #1 <i>"The policy/procedures Medication Errors (approved 1-12) and Non-Narcotic Medications used in Anesthesia (approved 1-12) failed to indicate that a medication error will be documented in the patient record when the medication was administered or omitted in error."</i></p> <p>FINDINGS #2</p>	03/01/2012	

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			<p><i>omitted in survey results</i> FINDINGS #3 "During an interview on 01-31-12 at 1105 hours, staff A1 confirmed that the policy/procedures lacked the requirement."</p> <p>RESPONSE 1 - 3 It is always been the practice of the Center to document all medications given. Incident reports are completed any time there is an error, whether it is one of omission or commission. The following verbiage was added to Policy PC 102 "Medications, Administration of": "Every drug error, whether one of omission or commission, will be charted and reported to the Director of the Center. An incident report must be completed and given to the director." These incident reports are discussed in the Safety Committee meetings and reported through the Quality Improvement Committee to the Medical Executive Committee and Governing Body to ensure ongoing compliance. This policy change documents the current practice of the Center. The policy change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. All staff members were educated on the policy change by 3-1-12.</p>		

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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, policy and procedure review, and staff interview, the facility failed to ensure the safety of patients related to the stability of stored/refrigerated medications, by failing to implement the facility policy for pharmacy refrigerator temperatures.</p> <p>Findings: 1. at 12:00 PM on 1/31/12, review of the policy and procedure "Medication Refrigerators", PC 093, indicated: a. under "Procedure", it reads: "...B. Refrigerators containing medication shall contain a thermometer and shall be kept between 36 degrees F and 46 Degrees F..."</p> <p>2. at 12:55 PM on 1/30/12, review of the "Pre-OP and PACU (post anesthesia care unit) Daily Checklist" in the company of</p>	S1146	<p>Tag S 1146410 IAC 15-2.5-7(b) (2) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based on document review, policy and procedure review, and staff interview, the facility failed to ensure the safety of patients related to the stability of stored/refrigerated medications, by failing to implement the facility policy for pharmacy refrigerator temperatures."</i></p> <p>FINDINGS #1 <i>"At 12:00 PM on 1/31/12, review of the policy and procedure "Medication Refrigerators", PC 093, indicated: a. under "Procedure", it reads: "...B. Refrigerators containing medication shall contain a thermometer and shall be kept between 36 degrees F and 46</i></p>	02/27/2012			

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	<p>staff member NC, indicated:</p> <p>a. in October 2011, 16 of 21 days the medication refrigerator was checked, were out of compliance with the 36 to 46 degree range required by facility policy (30 to 34 degrees)</p> <p>b. in November 2011, 1 day of patient care service lacked a pharmacy refrigerator temperature check and 12 of 19 days were below the recommended low of 36 degrees (32 to 34 degrees)</p> <p>c. in December 2011, 12 of 21 days were out of compliance with facility policy (30 to 34 degrees)</p> <p>d. in January 2012, 5 of 18 days were out of compliance with facility policy (26 to 34 degrees)</p> <p>3. at 3:15 PM on 1/30/12, interview with staff members NA and NB indicated:</p> <p>a. the refrigerator temperature logs have documentation of many days per month that the temperature checks were out of compliance with the facility policy</p> <p>b. the daily checklist had an area for staff to document an "action for failed result" that had been implemented to bring the refrigerator back into correct temperature range, but only had one note of action documented in October, no documentation in November, one note in December and 3 days of notation of corrective action in January</p> <p>c. in most instances, staff was failing to</p>		<p><i>Degrees F..."</i></p> <p>FINDINGS #2 "At 12:55 PM on 1/30/12, review of the "Pre-OP and PACU (post anesthesia care unit) Daily Checklist" in the company of staff member NC, indicated: a. in October 2011, 16 of 21 days the medication refrigerator was checked, were out of compliance with the 36 to 46 degree range required by facility policy (30 to 34 degrees)b. in November 2011, 1 day of patient care service lacked a pharmacy refrigerator temperature check and 12 of 19 days were below the recommended low of 36 degrees (32 to 34 degrees) c. in December 2011, 12 of 21 days were out of compliance with facility policy (30 to 34 degrees) d. in January 2012, 5 of 18 days were out of compliance with facility policy (26 to 34 degrees)"</p> <p>FINDINGS #3 "At 3:15 PM on 1/30/12, interview with staff members NA and NB indicated: a. the refrigerator temperature logs have documentation of many days per month that the temperature checks were out of compliance with the facility policy b. the daily checklist had an area for staff to document an "action for failed result" that had been implemented to bring the refrigerator back into correct temperature range, but only had</p>				

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	note any adjustment to refrigerator controls to meet the 36 to 46 degree requirement for medications d. the medications currently in the pharmacy refrigerator have been jeopardized with temperatures reaching below freezing, thus compromising patient safety in receiving these medications		<i>one note of action documented in October, no documentation in November, one note in December and 3 days of notation of corrective action in January c. in most instances, staff was failing to note any adjustment to refrigerator controls to meet the 36 to 46 degree requirement for medications d. the medications currently in the pharmacy refrigerator have been jeopardized with temperatures reaching below freezing, thus compromising patient safety in receiving these medications"</i> RESPONSE 1 - 3 The facility director revised the policy PC 093 – Medication Refrigerators on February 3, 2012 to include specific actions the employee must take upon discovering that a temperature reading is out of range, to correct the temperature, and the use of the correct chain of command to communicate this information as appropriate. When discovering an out of range reading, the policy change requires the staff member to seal the door firmly, check the temperature reading, temperature setting, and recheck the temperature in one-hour. If the temperature setting is incorrect, the employee is to fix the temperature, and document the action on the refrigerator log sheet. If the temperature remains out of range, the staff member must notify the director or		

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			<p>designee. The director revised the medication refrigeration daily log to include the re-checking of an out-of-range temperature in one hour, and a space to document the notification of the director of designee when a temperature is confirmed to be out of range.</p> <p>The director purchased a new refrigerator for the pharmacy on 01/30/12 in response to documented erratic temperature control. In addition, on 2/17/12 the director purchased and put a digital probe thermometer into place in the medication refrigerator. The device is programmed to text the director and chairperson of the Safety Committee whenever the temperature varies from the pre-set, desired range. The director reinforced the importance of documenting the refrigerator temperatures on the refrigeration log on each business day at a staff meeting on 02/17/12. The Medical Executive Committee, and Board approved the changes 02/27/12.</p> <p>Monitoring Compliance The director monitors compliance with the policy revision by 100% audit of the refrigerator logs each month. Parkview Biomedical department inspects the facility refrigerators annually, and will report any problems to the director.</p>		

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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 and interview, the center failed to ensure that a triennial analysis was performed on operational and maintenance records for the mechanical and physical plant equipment at the facility.</p> <p>Findings: 1. On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating a triennial analysis of operational and maintenance control records for heating, ventilation, air conditioning, fire alarm and/or smoke</p>	S1154	<p>Tag S 1154410 IAC 15-2.5-7(b)(3)(C) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to ensure that a triennial analysis was performed on operational and maintenance records for the mechanical and physical plant equipment at the facility."</i></p> <p>FINDINGS #1 <i>"On 1-30-12 at 1015 hours, staff A1 was requested to provide documentation indicating a triennial analysis of operational</i></p>	02/27/2012			

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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	
	<p>detector system was performed and none was provided prior to exit.</p> <p>2. Review of the maintenance schedules and equipment maintenance records failed to indicate that the center records were analyzed at least triennially.</p> <p>3. During an interview on 2-01-12 at 1010 hours, staff A1 confirmed that the center lacked documentation of a triennial analysis of the mechanical systems and equipment records.</p>		<p><i>and maintenance control records for heating, ventilation, air conditioning, fire alarm and/or smoke detector system was performed and none was provided prior to exit.."</i></p> <p>FINDINGS #2 <i>"Review of the maintenance schedules and equipment maintenance records failed to indicate that the center records were analyzed at least triennially."</i></p> <p>FINDINGS #3 <i>"During an interview on 2-01-12 at 1010 hours, staff A1 confirmed that the center lacked documentation of a triennial analysis of the mechanical systems and equipment records."</i></p> <p>RESPONSE 1 – 2 The Center documents operational and preventative maintenance on the services, as noted in findings #1, on a quarterly basis through the Quality Improvement Committee Data Collection Form according to the Center's Facility Plan entitled, "Utilities Management Plan" section entitled "Scheduled Maintenance and Inspections". These items are reported on quarterly through the QI Committee to the Medical Executive Committee and Governing Body. The facility plan is reviewed annually by the QI Committee, Medical Executive Committee, and Governing Body.</p>		

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			<p>The following verbiage was added to the "Utilities Management Plan" section entitled "Annual Review of the Utilities Management Plan": "The annual review will include an analysis of the operational and maintenance control records for the past year in order to establish any trends that may need to be addressed."</p> <p>This change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Ongoing compliance will continue to be documented through the QI Committee Data Collection Form and reported through the QI Committee to the Medical Executive Committee and Governing Body.</p>		

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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. Documentation titled Detailed Completed Work Order Report 01-01-2011 to 12-31-2011 for the center</p>	S1168	<p>Tag S 1168410 IAC 15-2.5-7(b)(4)(B)(iii) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: 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."</i></p> <p>FINDINGS #1 <i>"Documentation titled Detailed Completed Work Order Report 01-01-2011 to 12-31-2011 for the</i></p>	02/27/2012

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	<p>failed to indicate that ground current leakage testing was performed and recorded as either pass/fail or otherwise indicate the test measurements on the documentation for all indicated patient care equipment.</p> <p>3. During an interview on 2-01-12 at 1010 hours, staff A1 confirmed that triennial analysis of the patient care equipment PM was not being performed.</p> <p>4. During an interview on 2-01-12 at 1630 hours, staff A1 confirmed that the PM records lacked the required ground current leakage test result information.</p>		<p><i>center failed to indicate that ground current leakage testing was performed and recorded as either pass/fail or otherwise indicate the test measurements on the documentation for all indicated patient care equipment."</i></p> <p>FINDINGS #2 <i>Omitted from survey</i></p> <p>FINDINGS #3 <i>"During an interview on 2-01-12 at 1010 hours, staff A1 confirmed that triennial analysis of the patient care equipment PM was not being performed."</i></p> <p>FINDINGS #4 <i>"During an interview on 2-01-12 at 1630 hours, staff A1 confirmed that the PM records lacked the required ground current leakage test result information."</i></p> <p>RESPONSE 1 – 4 The Center contracts with Parkview Hospital Biomed Department to perform the required biomedical checks on all patient equipment. This contractor has been unable to provide the requested information to satisfy this regulation. Therefore, the Director of the Center contracted with the company named "Midwest Biomedical" to perform amperage leakage tests on all necessary equipment. The report documents that all tested equipment is within normal limits for leakage</p>		

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			<p>amperage. We are unable to provide a triennial analysis at this time because the previous biomedical company logs only pass/fail of amperage leakage and not numerical value. The report from the new biomedical company documents numerical values which will allow for required analysis. This data will be reported through the Safety Committee and QI Committee to the Medical Executive Committee and Governing Body.</p> <p>This change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Ongoing compliance will continue to be documented through the QI Committee Data Collection Form and reported through the QI Committee to the Medical Executive Committee and Governing Body.</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 Crash Cart (approved 1-12) lacked a description of the process for checking the defibrillator according to the manufacturer ' s recommendations. The center document Code Cart Checklist lacked a description of the 	S1170	<p>Tag S 1170410 IAC 15-2.5-7(b)(4)(B)(iv) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer."</i></p> <p>FINDINGS #1 <i>"The policy/procedure Crash Cart (approved 1-12) lacked a description of the process for checking the defibrillator according to the manufacturer's</i></p>	03/01/2012	

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	<p>process for checking the defibrillator according to the manufacturer ' s recommendations.</p> <p>3. The Physio-Control LifePak 20 service manual (2007 edition) indicated the following: " Table 7-1 lists the recommended maintenance and testing schedule ...complete Operator ' s Checklist [daily]. "</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>		<p><i>recommendations."</i></p> <p>FINDINGS #2 <i>"The center document Code Cart Checklist lacked a description of the process for checking the defibrillator according to the manufacturer's recommendations."</i></p> <p>FINDINGS #3 <i>"The Physio-Control LifePak 20 service manual (2007 edition) indicated the following: " Table 7-1 lists the recommended maintenance and testing schedule ...complete Operator ' s Checklist [daily]. "</i></p> <p>FINDINGS #4 <i>"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."</i></p> <p>RESPONSE 1 – 4 The Center's policy that directs the process for checking the defibrillator is PC 045 "Defibrillator Check" not "Crash Cart" as noted by the surveyor. It is the practice of the Center to test the defibrillators according to manufacturer's recommendations. The Code Cart Checklist includes instructions for daily checks as well as a record form to show</p>		

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			<p>what tasks were done to demonstrate that checks were completed. These tasks match the manufacturer's manual for recommended maintenance and testing.</p> <p>The following verbiage, as shown in red, was added to Policy PC 045 "Defibrillator Check": "To define the correct procedure for checking the defibrillator according to manufacturer's recommendations." This change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were notified of the policy change effective 3-1-12.</p>		

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S1174	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(5)(A)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(5) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:</p> <p>(A) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:</p> <p>(i) Asepsis. (ii) Cross-contamination prevention. (iii) Safe practice.</p> <p>Based on policy and procedure review, document review and staff interview, the facility failed to ensure the contracted housekeeping staff provided the environmental cleaning services requested/required.</p> <p>Findings: 1. at 9:00 AM on 1/31/12, review of the policy and procedure "Housekeeping", PC</p>	S1174	<p>Tag S 1170410 IAC 15-2.5-7(b)(4)(B)(iv) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to perform defibrillator inspection and testing as recommended by the manufacturer."</i></p> <p>FINDINGS #1</p>	03/01/2012			

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	<p>109, indicated:</p> <p>a. under "Policy", in item 4., it reads: "Supervision of cleaning in the non-restricted, semi-restricted areas will be supervised and inspected by the Director and the Housekeeping contract company."</p> <p>b. under "Policy", in item 6. F., it reads: "Annual walk thru inspections are completed."</p> <p>2. at 11:20 AM on 2/1/12, review of the document titled "Weekly Terminal Cleaning of Sterile Areas-Log" indicated:</p> <p>a. the form has blank areas for the "Week of" with a beginning date of the week and an ending date of the week to be noted by the housekeeping staff</p> <p>b. 3 forms were provided for review with 11/1/11 to 11/30/11 noted/documented at the top of the page; 12/1/11 to 12/31/11 on another; and 1/2012 to 1/31/12 noted on the last form</p> <p>3. interview with staff member NC at 11:20 AM on 2/1/12 indicated:</p> <p>a. the form/log says "Weekly Terminal Cleaning", but is for daily cleaning</p> <p>b. it is unknown why the housekeeping staff only documents cleaning on one form in a monthly manner when daily cleaning is to be documented</p> <p>c. this staff member has observed cleaning staff on occasion, while</p>		<p><i>"The policy/procedure Crash Cart (approved 1-12) lacked a description of the process for checking the defibrillator according to the manufacturer's recommendations."</i></p> <p>FINDINGS #2 <i>"The center document Code Cart Checklist lacked a description of the process for checking the defibrillator according to the manufacturer's recommendations."</i></p> <p>FINDINGS #3 <i>"The Physio-Control LifePak 20 service manual (2007 edition) indicated the following: " Table 7-1 lists the recommended maintenance and testing schedule ...complete Operator ' s Checklist [daily]. "</i></p> <p>FINDINGS #4 <i>"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."</i></p> <p>RESPONSE 1 – 4 The Center's policy that directs the process for checking the defibrillator is PC 045 "Defibrillator Check" not "Crash Cart" as noted by the surveyor. It is the practice of the Center to test the defibrillators according to</p>				

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	<p>remaining on site for 23 hours patients, but has never documented any observation that would indicate cleaning is being accomplished per facility requirements</p> <p>d. there is no documentation related to the "inspection" to be done by the Director as stated in the housekeeping policy</p> <p>e. there is no documentation that indicates "annual walk thru inspections" are being completed as per the housekeeping policy</p>		<p>manufacturer's recommendations. The Code Cart Checklist includes instructions for daily checks as well as a record form to show what tasks were done to demonstrate that checks were completed. These tasks match the manufacturer's manual for recommended maintenance and testing.</p> <p>The following verbiage, as shown in red, was added to Policy PC 045 "Defibrillator Check": "To define the correct procedure for checking the defibrillator according to manufacturer's recommendations." This change was presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were notified of the policy change effective 3-1-12.</p>		

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S1180	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.</p> <p>Based on document review and interview, the center failed to ensure its safety management program met regularly in compliance with program requirements and was composed of members appointed by the chief executive officer including representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. The center XI. Safety/Security Management Plan (approved 8-1) failed to indicate the composition of the committee and failed to indicate how often the committee would meet to conduct committee business.</p> <p>2. The Safety Committee Meeting</p>	S1180	<p>Tag S 1180 410 IAC 15-2.5-7(c) (1) PHYSICAL PLANT, EQUIPMENT MAINTENANCE <i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to ensure its safety management program met regularly in compliance with program requirements and was composed of members appointed by the chief executive officer including representatives from administration and patient care services." FINDINGS #1 "The center XI. Safety/Security Management Plan (approved 8-1) failed to indicate the composition of the committee and failed to indicate how often the committee would meet to conduct committee business." FINDINGS #2 "The Safety Committee Meeting minutes dated 6-27-11 and 7-26-11 failed to indicate what members were present. On 1-31-12 at 1145 hours, staff A2 indicated that minutes for a safety</i></p>	02/27/2012	

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	<p>minutes dated 6-27-11 and 7-26-11 failed to indicate what members were present. On 1-31-12 at 1145 hours, staff A2 indicated that minutes for a safety committee meeting on 10-10-11 were unavailable.</p> <p>3. During an interview on 2-01-12 at 1215 hours, staff A1 confirmed that the center policy/procedure lacked the indicated provisions.</p>		<p><i>committee meeting on 10-10-11 were unavailable.</i> FINDINGS #3 "During an interview on 2-01-12 at 1215 hours, staff A1 confirmed that the center policy/procedure lacked the indicated provisions." RESPONSE #1 It is the practice of the Center for the Safety Committee to meet at least quarterly. The following verbiage, as indicated in red, was added to the "XI. Safety / Security Management Plan" under section II.C.1.: "The Safety Committee will forward their quarterly Safety Committee minutes to the QI Committee." so that the written plan matches the current practice. RESPONSE #2 The Center utilizes a committee sign-in sheet to document meeting attendance. A sign-in sheet is present in the Safety Committee Meeting book for the dates 6-27-11 & 7-26-11. (copies included) below. Safety Committee meeting minutes from the 10-10-11 meeting have been completed and placed in the Safety Committee meeting book. RESPONSE #3 See response #1 AddendumOur safety committee has the following designated roles and individuals: Chris Butler, representing Administration, Lisa Glass, RN representing Patient Care, Justin Heffernan ST, representing Patient Care and are officially designated as these specific representatives ongoing.</p>		

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S1182	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(2)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Based upon document review and interview, the center failed to have a safety policy/procedure indicating an ongoing, center wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Findings:</p> <p>1. The policy/procedure XI Safety/Security Management Plan (approved 8-11) indicated the following: " Data is collected based on staff input and observation of the physical environment and testing and maintenance of the essential utilities systems. " The policy/procedure failed to indicate the process (who, what, when, where) for the ongoing collection of information about hazards in the workplace.</p> <p>2. The policy/procedure Risk</p>	S1182	<p>IDR</p> <p>Tag S 1182410 IAC 15-2.5-7(c) (2) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based upon document review and interview, the center failed to have a safety policy/procedure indicating an ongoing, center wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee."</i></p> <p>FINDINGS #1 <i>"The policy/procedure XI Safety/Security Management Plan (approved 8-11) indicated the following: "Data is collected based on staff input and observation of the physical environment and testing and maintenance of the essential utilities systems. "The policy/procedure failed to indicate the process (who, what, when, where) for the</i></p>	02/27/2012	

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	<p>Identification, Correction and Follow-Up (approved 1-12) lacked a provision for participation of the safety committee and/or quality improvement committee with the identified concern.</p> <p>3. During an interview on 2-01-12 at 1310 hours, staff A1 indicated that the Safety Plan and policy/procedures lacked the indicated provisions.</p>		<p><i>ongoing collection of information about hazards in the workplace."</i> FINDINGS #2 <i>"The policy/procedure Risk Identification, Correction and Follow-Up (approved 1-12) lacked a provision for participation of the safety committee and/or quality improvement committee with the identified concern.."</i> FINDINGS #3 <i>"During an interview on 2-01-12 at 1310 hours, staff A1 indicated that the Safety Plan and policy/procedures lacked the indicated provisions."</i></p> <p>X ISDH PAPER REVIEW RESOLUTION PROPOSED: Requesting that Tag S1182 be removed. We believe that the Center meets the intent of the regulation through the practice of the Safety Committee as outlined in the Facility Plan XI. Safety / Security Management Plan as noted below. Therefore, we request that consideration is given and this tag be removed.</p> <p>RESPONSE #1 The Center's Facility Plan "XI. Safety / Security Management Plan" details in section "VI. Monitoring of Safety / Security Plan" the process for what items/areas of the Center are monitored, frequency of monitoring, who does the monitoring and where the documentation is stored. (see below).</p>		

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			<p>VI. Monitoring of Safety / Security Plan</p> <p>A. Performance standards for Safety / Security are acknowledged through the following methods:</p> <ol style="list-style-type: none"> 1. staff testing and monitoring of inspection activities (i.e. crash cart, defibrillator), 2. the review of daily logs (i.e.; narcotics, sterilizers and disinfectants), 3. The review of center incident reports, maintaining product safety recall logs, and the review of preventive maintenance records. <p>B. Safety / Security management program data will be collected concurrently by the Safety Officer (i.e.; maintenance, Safety / Security, and risk management) and reviewed by the QI Committee on a quarterly basis.</p> <ol style="list-style-type: none"> 1. Data is collected based on staff input and observation of the physical environment and testing and maintenance of the essential utilities systems. 2. This review will ensure that certain performance standards are met and maintained. 3. The following table illustrates sources of data to be included in the analysis of the Safety / Security Management Plan. Other items may be needed as determined by the Safety Officer, Clinical Supervisor, Medical Executive Committee, or Governing Body. 		

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			<p>Data Source When and Where Reported Refer to: Incident Reports Internal Quarterly (Safety & QI Comm.) MEC Minutes Preventive Maintenance Records External Quarterly (Safety & QI Comm.) Contractor Manual Environmental Plant Safety Checklist Internal Monthly (Safety & QI Comm.) Safety Manual RESPONSE #2 The Center's Facility Plan "XI. Safety / Security Management Plan" details in section "II. Staff and Committee Members Roles" the roles and interaction of the Safety Committee and Quality Improvement Committee. It further details the communication of data to the Medical Executive Committee and Governing Body, who are ultimately responsible for all safety issues at the Center. (see below).</p> <p>II. Staff and Committee Members roles. Safety / Security is everyone's responsibility. The following roles have been established to identify those responsibilities.</p>		

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			<p>A. Responsibilities of Center Departments</p> <ol style="list-style-type: none"> Staff members are responsible for the Safety / Security of their respective areas. In the event that a disturbance arises, the Director / Clinical Supervisor or designee will be notified. At no time should Center employees place themselves in jeopardy. All disturbances will be documented using a Center Incident Report. All employees are responsible for the Safety / Security of their personal property while at the Center. <p>B. Role of the Safety Committee</p> <ol style="list-style-type: none"> The Safety Officer will report all Safety / Security incidents to the Safety Committee. The minutes of the Safety Committee will reflect investigations, actions taken, effectiveness of actions taken, and recommendations. <p>C. Role of the QI Committee</p> <ol style="list-style-type: none"> The Safety Committee will forward their Safety Committee minutes to the QI Committee The QI Committee will review the information and determine if any other recommendations are needed. It is the QI Committee's responsibility to determine if a QI Study is necessary based on the severity of the incident or if a pattern or trend can be 		

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			<p>established which may require a change in process.</p> <p>3. The QI Committee then reports the information and recommendations to the Medical Executive Committee and the Governing Body.</p> <p>D. Role of the Human Resources Consultant</p> <p>1. All applicants will be screened by use of employment applications and reference verifications to ensure that Center employees do not threaten the Safety / Security of the Center</p> <p>2. New employees will be oriented to the Center's Safety / Security Program by the Safety Officer at the time of their initial orientation period.</p>		

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S1188	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(4) A written fire control plan that contains provisions for the following:</p> <p>(A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of patients, personnel, and guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills.</p> <p>Based on document review and interview, the center failed to maintain and follow its policy/procedure for conducting quarterly fire drills for 1 of 4 required drills.</p> <p>Findings:</p> <p>1. The center Fire Safety, Prevention & Management Plan (approved 8-11) Fire Response/Code Red (approved 1-12) and Mock Fire Drill (approved 1-12) lacked a provision that an audible fire alarm will sound when conducting a fire drill per NFPA 101, 2000 Edition Chapter 21.7.1.2</p>	S1188	<p>Tag S 1188410 IAC 15-2.5-7(c) (4) PHYSICAL PLANT, EQUIPMENT MAINTENANCE</p> <p><i>"This RULE is not met as evidenced by: Based on document review and interview, the center failed to maintain and follow its policy/procedure for conducting quarterly fire drills for 1 of 4 required drills."</i></p> <p>FINDINGS #1 <i>"The center Fire Safety, Prevention & Management Plan (approved 8-11) Fire Response/Code Red (approved 1-12) and Mock Fire Drill (approved 1-12) lacked a provision that an audible fire alarm will sound when conducting a fire drill per NFPA 101, 2000</i></p>	03/01/2012			

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	<p>NFPA 101, 2000 Edition Chapter 21.7.1.2 indicates the following: [Fire exit drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with signals and emergency action required under varied conditions. When drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms.]</p> <p>2. The policy/procedure Mock Fire Drill (approved 1-12) indicated the following: " Fire drills will be performed quarterly ...The safety officer or designee will page overhead that a mock fire drill is being conducted ... and evacuate all personnel in a calm and orderly fashion ... account for all personnel once the staff has gathered by the front entrance sign in the East ...parking lot. " The policy/procedure lacked a provision for notifying the alarm monitoring service</p>		<p><i>Edition Chapter 21.7.1.2 NFPA 101, 2000 Edition Chapter 21.7.1.2 indicates the following: [Fire exit drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with signals and emergency action required under varied conditions. When drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms."</i></p> <p>FINDINGS #2 <i>"The policy/procedure Mock Fire Drill (approved 1-12) indicated the following: "Fire drills will be performed quarterly ...The safety officer or designee will page overhead that a mock fire drill is being conducted ... and evacuate all personnel in a calm and orderly fashion ... account for all personnel once the staff has gathered by the front entrance sign in the East ...parking lot." The policy/procedure lacked a provision for notifying the alarm monitoring service prior to conducting the drill and lacked a provision for validating the alarm signal transmission to the service during the drill performance."</i></p>				

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	<p>prior to conducting the drill and lacked a provision for validating the alarm signal transmission to the service during the drill performance.</p> <p>3. Center documentation failed to indicate that a fire drill was performed by day shift personnel for the period 7-1-11 through 9-30-11.</p> <p>4. The center document Fire Drill Evaluation (approved 1-12) lacked a provision for identifying the time that the drill was conducted and weather conditions present and failed to indicate if staff heard the overhead page that a drill was being conducted or if staff arrived safely and rapidly at the assembly point. The Evaluation tool failed to indicate which drill was evaluated when two drills were conducted on a single day and failed to indicate if patients were evacuated if present on the 3rd shift drill.</p> <p>5. On 1-31-12 at 1320 hours, staff A2 was requested to provide documentation of alternative training materials approved by the safety committee to validate fire disaster competency for part-time center staff not available to attend fire drills and none was provided prior to exit.</p>		<p>FINDINGS #3 "Center documentation failed to indicate that a fire drill was performed by day shift personnel for the period 7-1-11 through 9-30-11."</p> <p>FINDINGS #4 "The center document Fire Drill Evaluation (approved 1-12) lacked a provision for identifying the time that the drill was conducted and weather conditions present and failed to indicate if staff heard the overhead page that a drill was being conducted or if staff arrived safely and rapidly at the assembly point. The Evaluation tool failed to indicate which drill was evaluated when two drills were conducted on a single day and failed to indicate if patients were evacuated if present on the 3rd shift drill."</p> <p>FINDINGS #5 "On 1-31-12 at 1320 hours, staff A2 was requested to provide documentation of alternative training materials approved by the safety committee to validate fire disaster competency for part-time center staff not available to attend fire drills and none was provided prior to exit."</p> <p>FINDINGS #6 "During an interview on 1-31-12 at 1320 hours, staff A2</p>				

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	6. During an interview on 1-31-12 at 1320 hours, staff A2 confirmed that the Fire Safety Plan and policy/procedures lacked the indicated provisions.		<p><i>confirmed that the Fire Safety Plan and policy/procedures lacked the indicated provisions."</i></p> <p>RESPONSE 1 - 2</p> <p>While it has been the practice of the Center to sound an audible alarm and that is documented on the "Fire Drill Evaluation Form", changes have been made to the following documents to ensure compliance with this regulation in order to protect staff, patients, and visitors in the Center from injuries related to a fire situation.</p> <p>Policy EC 14 "Mock Fire Drill" has been revised to specifically detail how to conduct a fire drill including verbiage: "Fire drills must be documented (time, date, transmission of alarm, evaluation, etc. on the "Fire Drill Evaluation Form". (At least 75% of drills must include transmission equipment) 1" .</p> <p>Policy EC 14a "Fire Drill Evaluation Form" has been revised to include the following verbiage: Date: _____ Time: _____ Shift: _____ Person in Charge of Drill: _____</p> <p>Fire alarm activation Method: <input type="checkbox"/> Pull Station <input type="checkbox"/> Overhead Announcement (for use only between 2100 & 0600) Fire Alarm sounded appropriately: <input type="checkbox"/> Yes <input type="checkbox"/> No Was the Fire Alarm Reset: <input type="checkbox"/> Yes <input type="checkbox"/> No Monitoring Co. received signal at:</p>		

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			<p>_____ Verified by: _____</p> <p>RESPONSE #3 Policy EC 14 "Mock Fire Drill" has been revised to include the following verbiage on the frequency of fire drills: A. Fire drills will be performed at a minimum frequency of one per shift per quarter. 1 1. Drills conducted at shift change count for only one shift. 2. Staff must participate on the shift which they normally staff. (An RN that normally works nights should not attend day shift fire drills). These drills will be reported quarterly through the Safety Committee & QI Committee via their respective Data Collection Forms to ensure ongoing compliance.</p> <p>RESPONSE #4 Policy EC 14 "Mock Fire Drill" was revised to include the following verbiage which addresses scenarios of fire drills: B. Fire drills must be conducted under varying conditions (time during shift, location, type of fire, etc.). 1 1. This is to train staff in as many different scenarios as possible. 2. When 3 out of 4 fire drills are within an hour of each other it is viewed as establishing a pattern</p>	

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			<p>of non-compliance 1 .</p> <p>II. Fire Drill Scenarios</p> <p>A. The Director, Safety Officer, and/or designee will be in charge of the fire drill. Fire drills should be unannounced. Only staff involved in the staging of the fire drill scenario should have prior knowledge of the drill.</p> <p>B. Scenarios will be varied and specific to the Center. They will be designed to be as realistic as possible. Locations include the following:</p> <ol style="list-style-type: none"> 1. OR rooms 2. Pre/Post 3. Front Office 4. Autoclave room 5. Storage room <p>Policy 14a "Fire Drill Evaluation Form" has been revised to include the following verbiage to document scenarios: Unusual Conditions: (weather, remodeling, temporary exits): _____</p> <p>Drill Location and description of simulated condition: _____</p> <p>These fire drill evaluations will be reported on quarterly at the Safety Committee Meetings and QI Committee meetings via their respective Data Collection Forms to ensure ongoing compliance.</p> <p>FINDINGS 5 - 6 Policy EC 14 "Mock Fire Drill" has been revised to include the following verbiage in section IV. that directs alternative training</p>	

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			<p>for those unable to participate in the fire drill: B. Staff will sign in to document their attendance / participation in the fire drill.</p> <ol style="list-style-type: none"> Staff members who are unable to attend will be provided a packet of material to read & complete to substitute for the education / experience they would have gained by being present. The Director will try to schedule fire drills when the greatest number of staff are present in the building but with the least amount of interruption to patient flow and care. <p>These Policy and plan changes were presented and approved by the Medical Executive Committee and Governing Body on 2-27-12. Staff members were educated on the policy changes by 3-1-12.</p>		

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S1222	<p>410 IAC 15-2.5-8 RADIOLOGY SERVICES 410 IAC 15-2.5-8(e)</p> <p>(e) Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:</p> <p>(1) Proper safety precautions must be maintained against radiation hazards in accordance with the center's radiation and safety program(s).</p> <p>(2) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.</p> <p>Based on document review, the center failed to ensure that radiation hazard monitoring was periodically reviewed by the Radiation Safety Officer (RSO) to ensure that services were provided in a safe and effective manner and reported through the safety program.</p> <p>Findings:</p> <p>1. On 1-30-12 at 1015 hours, staff A1 was requested to provide copies of all radiation policies/procedures for the center.</p>	S1222	<p>Tag S 1222 410 IAC 15-2.5-8(e) RADIOLOGICAL SERVICES "This RULE is not met as evidenced by: Based on document review, the center failed to ensure that radiation hazard monitoring was periodically reviewed by the Radiation Safety Officer (RSO) to ensure that services were provided in a safe and effective manner and reported through the safety program." FINDINGS #1 "On 1-30-12 at 1015 hours, staff A1 was requested to provide copies of all radiation policies/procedures for the center." FINDINGS #2 "The policy/procedures Radiology Services and Fluoroscopy-Safety</p>	03/01/2012			

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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	
	<p>2. The policy/procedures Radiology Services and Fluoroscopy-Safety and Protection (approved 1-12) failed to indicate health care worker dosimetry monitoring reports will be reviewed by the RSO and reported through the safety program for the center.</p> <p>3. Dosimetry reports for 2011 lacked an indication or validation that they had been reviewed by either the RSO or the consultant radiologist for the center.</p> <p>4. The 2011 Safety Committee Minutes dated 4-11, 5-17, 6-27 and 7-26 failed to indicate that the RSO attended the meetings.</p> <p>5. The 2011 Safety Management Committee Reports 2nd Quarter and 3rd Quarter included a provision for dosimetry reporting and failed to indicate a safety standard or results of dosimetry reports for monitored staff.</p>		<p><i>and Protection (approved 1-12) failed to indicate health care worker dosimetry monitoring reports will be reviewed by the RSO and reported through the safety program for the center."</i></p> <p>FINDINGS #3 "Dosimetry reports for 2011 lacked an indication or validation that they had been reviewed by either the RSO or the consultant radiologist for the center." FINDINGS #4 "The 2011 Safety Committee Minutes dated 4-11, 5-17, 6-27 and 7-26 failed to indicate that the RSO attended the meetings." FINDINGS #5 "The 2011 Safety Management Committee Reports 2nd Quarter and 3rd Quarter included a provision for dosimetry reporting and failed to indicate a safety standard or results of dosimetry reports for monitored staff." RESPONSE 1 – 3 Policy PC 073 "Fluoroscopy – Safety and Protection" was revised to include the following verbiage: "The radiology technician will submit the x-ray badges to Landauer for evaluation every two months. The technician will inform the Director of high badge readings immediately upon discovery. The Director will alert the medical director and executive director. A reading of more than 417 mrem per one month or 834 mrem per two months indicates a higher than expected exposure to radiation and may be considered an unsafe exposure. If the badge reading</p>		

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			indicates a potential unsafe exposure, the radiation technician must immediately inform the center Director or designee. The Director/designee will investigate and complete an incident report The Director will notify the medical director and safety officer. The employee will be immediately referred to the Parkview Health System for evaluation of the existence and/or extent of the exposure.” The results of dosimetry badge readings will be documented on the Safety Committee Data Collection form. This will be reviewed by the Safety Committee and the Quality Improvement Committee each quarter. The Medical Executive Committee and Governing Body will receive reports through the QI Committee to ensure ongoing compliance. RESPONSE 4 A revised committee roster lists the radiology technician as part of the Safety Committee. RESPONSE 5 Policy PC 073 “Fluoroscopy – Safety and Protection” was revised to include the following verbiage: “A reading of more than 417 mrem per one month or 834 mrem per two months indicates a higher than expected exposure to radiation and may be considered an unsafe exposure. If the badge reading indicates a potential unsafe exposure, the radiation technician must immediately inform the center Director or designee.” to provide guidelines	

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			for dosimetry badge readings.	