

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001179	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/10/2014
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NAME OF PROVIDER OR SUPPLIER ELKHART DAY SURGERY, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 2746 OLD US HIGHWAY 20 WEST ELKHART, IN 46514
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S000000	The visit was for a licensure survey. Facility Number: 012596 Survey Date: 9-8/10-14 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor Marcia Anness, RN Public Health Nurse Surveyor QA: cloughlin 09/23/14	S000000		
S000156	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E) Require that the chief executive officer develop and implement policies and programs for the following: (E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care			

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

TITLE

(X6) DATE

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

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	<p>or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on policy review, personnel file review and interview, the facility failed to ensure that performance appraisals were completed on 7 of 7 staff.</p> <p>Findings:</p> <p>1. Review of policy and procedure, "Performance Appraisal", with approval date of 5/3/12 indicated:</p> <p style="padding-left: 40px;">a. Under "Policy", it read: "It is the policy of Elkhart Day Surgery to periodically and routinely evaluate the job performance of each employee. This evaluation will be carried out according to the time tables given below and will be objectively based on criteria set forth in the job description for each position.</p> <p style="padding-left: 80px;">- Three months (90 calendar days) after each new employee begins work.</p> <p style="padding-left: 80px;">- One year from employee's initial date of employment.</p> <p style="padding-left: 80px;">- Each employee is evaluated annually thereafter on his/her anniversary date. "</p> <p>2. Review of staff personnel files indicated:</p> <p style="padding-left: 40px;">a. Staff #N1 (RN) annual performance appraisal due 4/10/14 was not present.</p> <p style="padding-left: 40px;">b. Staff #N2 (RN) annual</p>	S000156	<p>(E) 1. The Performance appraisals on all staff will be done by 10/9/2014. The completed Performance Appraisals will be placed in the employee's personnel file.(E) 2. The policy "Performance Appraisal" will be revised to state that the Ninety (90) day Probationary Appraisal for New Employees will be done as needed. This report can be used to show either satisfactory or unsatisfactory completion of this period. This will be prevented in the future by the use of a perpetual calendar of staffs' requirements for their personnel files. This policy will be reviewed with the facility staff, the Medical Advisory Committee and the Governing Body. The Governing Body approved this revision.(E) 3. The responsible party is the Director of Nursing.</p>	10/09/2014

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S000310	<p>performance appraisal due 4/12/14 was not present.</p> <p>c. Staff #N3 (RN) annual performance appraisal due 4/20/14 was not present.</p> <p>d. Staff #N4 (tech) 90 day performance appraisal due 7/30/14 was not present.</p> <p>e. Staff #N5 (RN) annual performance appraisal due 4/12 14 was not present.</p> <p>f. Staff #N6 (RN) annual performance appraisal due 4/12/14 was not present.</p> <p>g. Staff #N7(DON) annual performance appraisal due 8/19/14 was not present.</p> <p>3. At 4:00 PM on 9/8/14 , staff member #N7 (DON) verified that staff #N1, 2, 3, 5, 6, 7 have not received an annual performance appraisal. Staff #N4 has not received a 90 day performance appraisal.</p> <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>						

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	<p>Based on document review and interview, the center failed to follow its policies and procedures and ensure that its contracted services were evaluated and reviewed by the Quality Assessment and Performance Improvement (QA) program for 14 of 20 contracted services.</p> <p>Findings:</p> <p>1. The policy/procedure Quality Assessment and Performance Improvement (approved 6-14) indicated the following: "The Governing Body requires the medical staff to implement and report on the activities and the mechanisms for monitoring, assessing and evaluatingthose departments/disciplines that have direct or indirect affect on patient care, including ...contracted services. The Governing Body requires the detail and frequency of data collection for all indicators and performance processes (as outlined in this program) ...will be reported to the Medical Advisory Committee on a quarterly basis ..."</p> <p>2. Review of the Medical Advisory Committee (MAC) minutes dated 6-05-13, 9-25-13, 12-18-13, 3-12-14 and 6-19-14 failed to indicate documentation that any contracted services were evaluated and reviewed during the MAC</p>	S000310	(1) 1. A Contracted Services Evaluation Form will be developed and completed quarterly by the Director of Nursing. This form will be reviewed at the Medical Advisory Committee Meeting and the Governing Body meeting quarterly. The Governing Body reviewed and approved this form. (1) 2. The Contracted Services Evaluation Form will prevent this deficiency from reoccurring.(1) 3. The Director of Nursing is responsible.	10/10/2014	

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	<p>meetings.</p> <p>3. The governing board minutes dated 6-05-13, 9-25-13, 12-18-13, 3-12-14 and 6-19-14 failed to indicate that the contracted service providers for 14 services (biohazardous waste, heating/air conditioning, housekeeping, laboratory/pathology, laser service, lens provider, laundry, medical gas, medical records consultant, medical transcription, pest control, pharmacy consultant, sterilizer, and a waste disposal service) were evaluated and reviewed. The minutes indicated that the reports provided by the laboratory/pathology service, the medical records consultant, and the pharmacist consultant were reviewed, and no documentation indicated that the providers of the reports were periodically evaluated.</p> <p>4. Review of center documentation indicated the following: biohazardous waste disposal by CS1, heating and air conditioning service by CS2, housekeeping services by CS3, laboratory/pathology services by CS4, laser service by CS5, lens provider by CS6, laundry service by CS7, medical gas by CS8, medical record consulting by CS9, medical transcription by CS10, pest control service by CS11, pharmacy consulting by CS12, sterilizer service by</p>						

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S000428	<p>CS13, and waste disposal service by CS14.</p> <p>5. During an interview on 9-10-14 at 1120 hours, the director of nursing A2 confirmed that the 14 contracted services were not being evaluated or reviewed through the QA program.</p> <p>6. During an interview on 9-10-14 at 1245 hours, the administrator A1 confirmed that the governing board documentation indicated that the reports provided by the the medical records consultant and the pharmacist consultant were reviewed and confirmed that no documentation indicating the periodic evaluation of the 2 service providers was available.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation. Based on document review, observation</p>	S000428	(E) (i) 1. The policy/procedures	10/09/2014			

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	<p>and interview, the infection control (IC) committee failed to maintain its sanitation policy/procedures and failed to ensure that the operating room (OR) cleaning was performed in a safe and effective manner.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedures titled Environment: OR Sanitation (approved 6-14) and Environment: Housekeeping Standards (approved 6-14) failed to indicate the following: <ol style="list-style-type: none"> A. IC committee review and approval B. the IC committee-approved disinfectants to be used for cleaning and disinfecting the OR suite C. a provision ensuring that all high-touch surfaces were cleaned and/or disinfected D. a specific process for surgery suite cleaning to ensure that all surfaces were cleaned in a manner to prevent contamination of previously disinfected surfaces 2. During an interview on 9-09-14 at 1500 hours, the director of nursing A2 confirmed that the policy/procedures lacked the indicated provisions. 3. During a tour on 9-09-14 at 1130 hours, the following condition was 		<p>titled "Environment: OR Sanitation" and "Environment: Housekeeping Standards" will be revised to include the Infection Control committee's review and approval of the policies/procedures, the Infection Control committee's approval of EPA-registered disinfectants to be used for cleaning and disinfecting the OR suite, a provision ensuring that all high-touch surfaces are cleaned and/or disinfected, and a specific process for surgery suite cleaning to ensure that all surfaces are cleaned in a manner to prevent contamination of previously disinfected surfaces. These policies/procedures and processes will be reviewed with facility staff and housekeeping staff, as well as the Medical Advisory Committee and Governing Body. The Governing Body approved these revisions. (E) (i) 2. This will be prevented from recurring in the future by evaluation of the cleaning quarterly by the Director of Nursing or Infection Control Coordinator. The results of these evaluations will be shared with the facility and housekeeping staff, as well as, the Infection Control Committee, the Medical Advisory Committee and Governing Body. The facility and housekeeping staff will receive additional training if needed as a result of these evaluations.(E) (i) 3. The Director of Nursing, the</p>				

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	<p>identified in the minor procedure room: accumulated dust and particulate material was observed on the angled top of a metal storage cabinet.</p> <p>4. During an interview on 9-09-14 at 1130 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the cabinet.</p> <p>5. During a tour on 9-09-14 at 1140 hours, the following condition was identified in OR room 2: accumulated dust and particulate material was observed on the angled top of a metal storage cabinet.</p> <p>6. During an interview on 9-09-14 at 1140 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the cabinet.</p> <p>7. During an observation on 9-09-14 at 1150 hours, the following conditions were identified in OR room 1: accumulated dust and particulate material was observed on the top of the microscope #1 support arm. Accumulated dust and particulates were also observed on the top surface of the anesthesia machine and the upper ledge of the wall-mounted xray film viewer.</p>		Infection Control Coordinator and the Governing Body are responsible.				

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S000442	<p>8. During an interview on 9-09-14 at 1150 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the OR equipment and surfaces and confirmed that the OR room cleaning had not been performed in a safe and effective manner.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(viii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on policy review, personnel file review and interview, the facility failed to determine the communicable disease status of newly hired staff in 2 of 7 personnel files reviewed.</p> <p>Findings:</p>	S000442	(E) (viii) 1. The staff's personnel files will be reviewed to ensure that all staff members have proof of their immunization status for measles, mumps, varicella and rubella in their personnel files. The two staff members that did not have their immunization status in their personnel files will give the Director of Nursing a	10/09/2014

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S000446	<p>1. Review of policy and procedure "Employee Health Program" with revised date of 9/25/13 indicated:</p> <p>a. Under "New employee health screening will be performed before the employee begins work and may include the following:</p> <ul style="list-style-type: none"> - Doctor's note, proof of vaccination or titer for measles, mumps, varicella and rubella." <p>2. Review of staff personnel files indicated:</p> <p>a. Staff #N4 (tech) rubella, rubeola and varicella immunization status not present.</p> <p>b. Staff #N6 (RN) rubella, rubeola and varicella immunization status not present.</p> <p>3. At 4:00 PM on 9/8/14, staff member #N7 (DON) verified that the facility did not have the immunization status for staff member #N4 and N6.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(x)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and</p>		<p>Doctor's note or proof of vaccination of measles, mumps, varicella and rubella, or the Director of Nursing will have titers drawn on the two employees before they return to work. Copies of these will be placed in each employee's personnel file. (E) (viii) 2. This will be prevented in the future by the use of a perpetual calendar of staffs' requirements for their personnel files.(E) (viii) 3. The responsible party is the Director of Nursing.</p>				

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	<p>programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(x) A program of linen management. Based on document review and interview, the center failed to monitor and review the commercial laundry service provider through the infection control program.</p> <p>Findings:</p> <p>1. On 9-08-14 at 1200 hours, the director of nursing A2 was requested to provide documentation indicating that temperature and titration reports obtained from the commercial laundry service provider were periodically reviewed through the infection control program and none was provided prior to exit.</p> <p>2. The governing board minutes dated 12-18-13, 3-12-14 and 6-19-14 failed to indicate that a review of commercial laundry temperature and titration reports was performed under the subject heading 'G' titled Infection Control.</p> <p>3. During an interview on 9-10-14 at 1135 hours, the director of nursing A2 confirmed that the board minutes failed to indicate that the temperature and titration reports were reviewed and no other documentation was available.</p>	S000446	<p>(E) (x) 1. The Director of Nursing will receive quarterly temperature and titration reports from the commercial laundry service provider. These reports will be reviewed by the Infection Control Committee, the Medical Advisory Committee and the Governing Body. The policy "Infection Control" will be revised to include linen management. The policy "Laundry Care of Reusable Scrubs/Linen" will be revised to include the handling, processing, and transporting of clean and soiled linen by linen and laundry personnel. These policies will be reviewed with staff and the commercial laundry service provider, as well as, the Infection Control Committee, the Medical Advisory Committee and the Governing Body. The Governing Body approved these revisions.</p> <p>(E) (x) 2. The deficiency, with respect to the policies, will not recur as policies will only be revised after review and approval by the Governing Body. (E) (x) 3. The Director of Nursing and Governing Body are responsible.</p>	10/09/2014

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S000466	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(3)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not limited to, the following:</p> <p>(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.</p> <p>(B) Results of biological indicators used in testing the sterilizing processes.</p> <p>Based on document review and interview, the infection control committee failed to ensure that records of sterilization processes and biological testing were reported at Infection Control Committee meetings, and Quality meetings, for four of the last meetings reviewed.</p> <p>Findings: 1. Review of the Governing Board meeting minutes, which includes infection control committee and quality</p>	S000466	(3) (A) and (B) 1. The daily records of the sterilization cycle for sterilizer load and the results of biological indicators used in testing the sterilizing processes will be reported to the Infection Control Committee, the Medical Advisory Committee and the Governing Body quarterly. The policy "Infection Control" will be revised to include the addition of the review of the daily records of the sterilization cycle for sterilizer load and the results of biological indicators used in testing the sterilizing processes. The policy	10/09/2014

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S000612	<p>committee issues and reports, indicated that the following meetings lacked evaluation of the sterilization and biological processes for the facility:</p> <p>a. 9/25/13 b. 12/18/13 c. 3/12/14 d. 6/19/14</p> <p>2. Interview with staff member #55, the co-infection control practitioner, at 9:00 AM on 9/10/14 indicated: the sterilization and biological processes for the facility are not currently being evaluated and discussed at the Governing Board/Body meetings where infection control items/practices are brought forth.</p> <p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(c)(1)</p> <p>(c) An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.</p> <p>Based on policy review, medical record review, and staff interview, the facility</p>	S000612	<p>"Sterilization Monitoring" will be revised to include the reporting of the daily records of the sterilization cycle for sterilizer load and the results of biological indicators used in testing the sterilizing processes to the Infection Control Committee, the Medical Advisory Committee and the Governing Body quarterly. These policies will be reviewed with the facility staff, the Infection Control Committee, the Medical Advisory Committee and the Governing Body. The Governing Body approved these revisions. (3) (A) and (B) 2. The deficiency, with respect to the policies, will not recur as policies will only be revised after review and approval by the Governing Body. (E) (A) and (B) 3. The Director of Nursing and Governing Body are responsible.</p> <p>(c) (1) 1. The survey findings were reviewed with the facility</p>	10/09/2014			

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	<p>failed to ensure the accuracy of medical records for 5 of 29 records reviewed (pts. N3, N6, N7, N13, and N19).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of the policy "Documentation Standards", no policy number, last approved on 6/19/14, indicated: <ol style="list-style-type: none"> a. Under "Entry Guidelines" on page 2, it reads: "All entries in the medical record shall be consistent with the following guidelines:...Clear, concise, factual, objective and accurate..." 2. Review of medical records indicated: <ol style="list-style-type: none"> a. Pt. N3 had surgery on 8/5/14 for a right and left eye blepharoplasty (upper), documentation on the Anesthesia record indicated the pre op diagnosis was a "cataract", while the surgeon's pre op diagnosis was "Upper lid dermatocholasis, Right and Left eye". b. Pt. N6 had a Burke Levator procedure done on the right eye on 8/20/14, but had documentation in the EMR (electronic medical record) indicating that "Specific Discharge Instructions" given were for a "Cataract", not a Burke Levator procedure. c. Pt. N7 had a Yag Capsulotomy on 8/27/14 with documentation as follows: <ol style="list-style-type: none"> A. That the procedure was performed under "local Anesthesia", as listed in the pre operative portion of the medical 		<p>staff, anesthesia providers and physician. The policy "Documentation Standards" was reviewed with the facility staff, anesthesia providers and physician. They were reminded to review their patient's records at the end of the day to make sure they are accurate and complete. (c) (1) 2. The Director of Nursing will periodically review the patients' EMRs to ensure accuracy and completeness to prevent this from recurring. The Director of Nurisng will review any deficiencies with the staff involved.(c) (1) 3. The Director of Nursing is responsible.</p>	

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	<p>record, in the patient's consent form, and in the "procedure" portion where it was noted that "topical Tetracaine" was used, but had post op documentation where it was listed that "Monitored Anesthesia Care" was the anesthesia type utilized.</p> <p>B. "Specific Discharge Instructions" were listed as for a "Cataract", not a Yag procedure.</p> <p>d. Pt. N13 was to have cataract surgery on 8/19/14 and had:</p> <p>A. A pre op phone call in which the "Eye for Procedure" was listed as "Right Eye".</p> <p>B. A Pre op note that listed the "procedure" as "Left Eye Cataract Extraction..."</p> <p>C. On the same page as in B. above, the "Eye for Procedure was listed as "Right Eye".</p> <p>D. The consent was written and signed for a "Left Eye Cataract Extraction...".</p> <p>E. The operative report indicated that the patient had "Anesthesia" as "Monitored Anesthesia Care", when, in fact, the patient had pre operative notes for "No IV (intravenous), locale (sic) anesthesia only" due to an elevated blood sugar and consultation with the anesthesiologist prior to surgery. The operative room nursing record states: "Anesthesia: Local Anesthesia and Topical Tetracaine Drop".</p> <p>e. Pt. N19 had cataract surgery on</p>			

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S000732	<p>8/27/14 with inaccurate documentation as follows:</p> <p>A. The Pre op information forms, surgical consent form, and intra operative notes, indicated the patient was having "Left Eye Cataract extraction...".</p> <p>B. The "Anesthesia Record" documentation listed the "Procedure" as "Right Eye Cataract Extraction...".</p> <p>3. At 11:15 AM and 12:35 PM on 9/9/14, interview with staff member #55, the director of nursing, indicated:</p> <p>a. Inaccuracy in the medical records, as listed in 2. above was confirmed.</p> <p>b. When patients have one eye's cataract extraction, and then come in for the other eye, staff sometimes forget to correct the EMR to the correct site.</p> <p>c. The EMR also lists discharge instructions for the previous procedure performed, which requires staff to make a change in the EMR indicating the correct discharge instructions given.</p> <p>d. Facility staff need to be more careful in reviewing the automatically populated sections of the EMR to be sure that accurate documentation occurs.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p>						

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	<p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially. Based upon document review and interview, the medical staff failed to follow its bylaws and ensure that an annual review of the medical staff bylaws, rules and regulations was performed.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (last reviewed 5-03-12) indicated the following: " The duties of the Medical Advisory Committee shall be to ... review medical staff bylaws and rules and regulations annually ... "</p> <p>2. The medical advisory committee (MAC) minutes provided for review dated 6-05-13, 9-25-13, 12-18-13, 3-12-14 and 6-19-14 failed to indicate that he committee reviewed the medical staff bylaws on an annual basis as proscribed.</p> <p>3. During an interview on 9-10-14 at 1215 hours, the administrator A1 confirmed that the medical staff failed to follow its bylaws and confirmed that no documentation indicating the annual approval of the medical staff bylaws, rules and regulations by the MAC was</p>	S000732	<p>(2) 1. The policies and procedures had been reviewed and approved in June 2014. The Medical Staff Bylaws and Medical Staff Rules and Regulations were in a policy and procedure manual that was reviewed and approved, but it was not documented separately in the Medical Advisory Committee Meeting and Governing Body Meeting Minutes. The Medical Staff Bylaws and Medical Staff Rules and Regulations will be documented as being reviewed and approved separately in the future. (2) 2. The deficiency, with respect to policy, will not recur as policies will only be revised after review and approval by the Governing Body. (2) 3. The Director of Nursing and Governing Body are responsible.</p>	10/09/2014			

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S000780	<p>available.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based on review of patient medical records and staff interview, the medical staff failed to give specific pre op orders, related to saline locks, for 18 of 18 patients who had cataract procedures, and 5 of 5 patients who had blepharoplasty procedures, per standards of practice (23 of 29 patients total...pts. N1, N2, N3, N4, N5, N8, N10, N11, N12, N13, N14, N15, N16, N17, N18, N19, N20, N22, N24, N25, N26, N27, and N30).</p> <p>Findings: 1. Review of medical records N1, N2, N3, N4, N5, N8, N10, N11, N12, N13, N14, N15, N16, N17, N18, N19, N20,</p>	S000780	(3) (N) 1. After reviewing the Ambulatory Rules and Guidelines with Dr. Boling, the Pre-Op order in the patient's EMR will be revised to specify Start saline lock with 22G or 24G insyte and flush with 1-3cc of .9%NS for the cataract patients and Start IV with 22G or 24G insyte of .9%NS 500ml at KVO for the other major surgery patients. This revised order will be reviewed with all facility staff, the Medical Advisory Committee, and the Governing Body. This was approved by the Governing Body. (3) (N) 2. This will be prevented from recurring in the future because orders will only be revised after review and approval	10/09/2014			

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S001040	<p>N22, N24, N25, N26, N27, and N30 indicated:</p> <p>a. All of the pre op orders read: "...Start Saline lock prn (as needed)".</p> <p>2. At 3:45 PM on 9/9/14, interview with staff member #55, the director of nursing, indicated:</p> <p>a. The only cataract patients who wouldn't have a Saline lock started are those who have the procedure performed under local anesthetic, instead of monitored anesthesia.</p> <p>b. Most times, a 22 gauge or 24 gauge needle is used to start the IV access, and 3 cc of normal saline is used to flush this access line once started.</p> <p>c. The current standing orders do not specify a size of saline lock to use, nor is there an order related to what liquid to use for flushing, or the amount to use.</p> <p>d. The standing orders lack specificity, as is a standard of practice.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAc 15-2.5-6(3)(F)</p> <p>Pharmaceutical service must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained,</p>		by the physician and Governing Body.(3) (N) 3. The Director of Nursing is responsible.				

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	<p>and made available to personnel, including, but not limited to, the following:</p> <p>(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.</p> <p>Based on review of the medical staff rules and regulations, policy review, medical record review, and interview, the facility failed to follow their rules and regulations, and facility policy, related to the dispensing of drugs, and/or samples, for 3 (patients N3, N6 and N8) of 7 patients who had specialty procedures performed and who received samples when discharged from the PACU (post anesthesia care unit).</p> <p>Findings:</p> <p>1. Review of the Medical Staff Rules and Regulations, last approved 5/3/12, indicated:</p> <p>a. On page two, under "Drugs", it reads: "...No drugs will be dispensed from [the facility]."</p> <p>2. Review of the policy "Medication Storage", no policy number, last approved on 6/19/14, indicated:</p> <p>a. On page two, the last bullet point reads: "Sample Medications: Under no circumstances will sample medications be received, stored or dispensed in this</p>	S001040	<p>(F) 1. The Medical Staff Rules and Regulations will be revised to state that the Instructions to the patient on the use of take home medications is the responsibility of the prescribing physician. The policy "Medication Storage" will be revised to state that the Instructions to the patient on the use of take home medications is the responsibility of the prescribing physician. These revisions will be reviewed with the facility staff, the Medical Advisory Committee, and the Governing Body. The Governing Body approved these revisions.</p> <p>(F) 2. The deficiency, with respect to the policies, will not recur as policies will only be revised after review and approval by the Governing Body. (F) 3. The Director of Nursing and Governing Body are responsible.</p>	10/09/2014

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S001142	<p>facility."</p> <p>3. Review of patient medical records indicated that 2 of 5 patients who had a blepharoplasty and 1 of 2 who had a Burke Levator procedure (3 of 7 patients total) had PACU documentation as follows:</p> <p>a. For pt. N3: "Sample of Polycin ointment given to Pt. by Dr...to apply to suture lines 3 times a day."</p> <p>b. For pt. N6: "3:14 PM Dr...gave a sample of polymyxin ointment to take home."</p> <p>c. For pt. N8: "Sample of Polycin ointment given by Dr...to pt."</p> <p>4. At 12:35 PM on 9/9/14, interview with staff member #55, the director of nursing, indicated:</p> <p>a. There is a discrepancy between the medical staff rules and regulations, which states that drugs will not be dispensed, the medication policy which states that Sample medications will not be stored or dispensed, and the fact that the physician is giving ointment to patients in the PACU to take home with them, as written in 3. above.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)</p>						

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	<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>(1) No condition in the center or on the grounds may be maintained which may be conducive to the harboring or breeding of insects, rodents, or other vermin.</p> <p>Based on observation and interview, the center failed to ensure that its environment of care was maintained free of insects and related contaminants for 2 of 3 patient areas (pre and post procedure area and the restricted surgery area) at the center.</p> <p>Findings:</p> <p>1. During an observation on 9-09-14 at 1025 hours, the following condition was identified in the pre and post procedure area: multiple 24" by 48" ceiling light fixtures were observed to contain the remains of approximately 17 insects.</p> <p>2. During an observation on 9-09-14 at 1200 hours, the following condition was identified in the soiled central reprocessing room: a 24" by 48" ceiling light fixture was observed to contain the remains of 2 insects.</p>	S001142	<p>(b) (1) 1. The policy "Pest Control" will be revised to include monitoring of the environment by the facility's staff. Pest control problems shall be reported promptly. The Environmental Surveillance Report which is done quarterly will be revised to include detection of pests. These revisions will be reviewed with the facility staff, the Medical Advisory Committee, and the Governing Body. The Governing Body approved these revisions.</p> <p>(b) (1) 2. The deficiency, with respect to the policy, will not recur as policies will only be revised after review and approval by the Governing Body. (b) (1) 3. The Director of Nursing and Governing Body are responsible</p>	10/09/2014

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S001146	<p>3. During an interview on 9-09-14 at 1200 hours, the director of nursing A2 and facilities manager A6 confirmed that the lighting fixture condition was unsanitary and confirmed that the patient care and restricted surgery areas had not been properly maintained.</p> <p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation and interview, the center failed to ensure that the restricted surgery environment was maintained to minimize the risk of hazards to patients and personnel at the center.</p> <p>Findings:</p> <p>1. During a tour of the center on 9-09-14 at 1200 hours, the following condition was identified in the soiled</p>	S001146	(b) (2) 1. All facility staff will be instructed to keep the pass-through window closed at all times, except when instruments and equipment are being transferred to the sterilizing room. The automatic door closers will be repaired in OR 1, OR 2, and the common surgery corridor.(b) (2) 2. The Director of Nursing, when doing the quarterly Environmental Surveillance Report, will make sure the above issues are not recurring.(b) (2) 3.	10/09/2014

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	<p>central reprocessing room: an open 24" by 36" pass-through window was observed between the decontamination room and the instrument packaging and sterilizing room.</p> <p>2. During an interview on 9-09-14 at 1200 hours, the director of nursing A2 confirmed that the window should remain closed at all times except when instruments and equipment are being transferred to the sterilizing room.</p> <p>3. During a tour on 9-09-14 at 1208 hours, the following condition was identified in the substerile central reprocessing room: three (3) disconnected automatic door closers were observed on the 3 doors connecting with OR1, OR2, and the common surgery corridor. Therefore, it could not be determined that the special ventilation provisions and room-to-room ventilation requirements for the operating rooms, instrument decontamination and reprocessing rooms were not compromised when patients were present at the center.</p> <p>4. During an interview on 9-09-14 at 1208 hours, the director of nursing A2 confirmed that the door closer units needed to be repaired or replaced.</p>		The Director of Nursing is responsible.				

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S001172	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(5)</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: Based on document review, observation and interview, the center failed to maintain its operating rooms (OR) and restricted access areas in a clean and sanitary manner for its 2 OR rooms, a minor procedure room and the central reprocessing area of the center.</p> <p>Findings:</p> <p>1. The policy/procedure Environment: Housekeeping Standards (approved 6-14) indicated the following: " End of Day ...Wipe all furniture and equipment in the OR suite, such as instrument table, kick buckets, mayo stand, trash container, surgery lights, OR table, stools, etc ... "</p> <p>2. During a tour on 9-09-14 at 1130</p>	S001172	<p>(b) (5) 1. The policy/procedures titled "Environment: OR Sanitation" and "Environment: Housekeeping Standards" will be revised to include a process ensuring that all high-touch surfaces are cleaned and/or disinfected, and a specific process for cleaning to ensure that all surfaces are cleaned in a manner to prevent contamination of previously disinfected surfaces. These policies/procedures and processes will be reviewed with facility staff and housekeeping staff, as well as the Medical Advisory Committee and Governing Body. The Governing Body approved these revisions.</p> <p>(b) (5) 2. This will be prevented from recurring in the future by evaluation of the cleaning quarterly by the Director of</p>	10/09/2014
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	<p>hours, the following condition was identified in the minor procedure room: accumulated dust and particulate material was observed on the angled top of a metal storage cabinet.</p> <p>3. During an interview on 9-09-14 at 1130 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the cabinet.</p> <p>4. During a tour on 9-09-14 at 1140 hours, the following condition was identified in OR room 2: accumulated dust and particulate material was observed on the angled top of a metal storage cabinet.</p> <p>5. During an interview on 9-09-14 at 1140 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the cabinet.</p> <p>6. During an observation on 9-09-14 at 1150 hours, the following conditions were identified in OR room 1: accumulated dust and particulate material was observed on the top of the microscope #1 support arm. Accumulated dust and particulates were also observed on the top surface of the anesthesia machine and the upper ledge</p>		<p>Nursing or Infection Control Coordinator. The results of these evaluations will be shared with the facility and housekeeping staff, as well as, the Infection Control Committee, the Medical Advisory Committee and Governing Body. The facility and housekeeping staff will receive additional training if needed as a result of these evaluations. (b) (5) 3. The Director of Nursing, the Infection Control Coordinator and the Governing Body are responsible.</p>				

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S001174	<p>of the wall-mounted xray film viewer.</p> <p>7. During an interview on 9-09-14 at 1150 hours, the director of nursing A2 and facilities manager A6 confirmed the presence of accumulated dust on the OR equipment and surfaces.</p> <p>8. During an observation on 9-09-14 at 1203 hours, the following condition was identified in the substerile central reprocessing room: accumulated white dust and particulate matter was observed on the top edge of the countertop backsplash near the corner adjacent to OR room 1.</p> <p>9. During an interview on 9-09-14 at 1150 hours, the director of nursing A2 confirmed the presence of accumulated dust on the countertop surface and confirmed that the operating rooms and substerile areas had not been maintained.</p> <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>						

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	<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, observation, and interview, the facility failed to ensure cleanliness in 3 areas toured.</p> <p>Findings:</p> <p>1. Review of the policy "Pre OP (operative)/PACU (post anesthesia care unit) Sanitation", no policy number, last approved on 6/19/14, indicated: a. Under "Monthly", it read: "...Refrigerators are cleaned."</p> <p>2. Review of the policy "Environment: Housekeeping Standards", read on page 3, under "Preop and PACU...Monthly:...Clean refrigerator...".</p> <p>3. Review of the policy "Medication</p>	S001174	(b) (5) (A) 1. While on tour with the Surveyor, the Director of Nursing was unsure if there was a form that documented the Refrigerator Cleaning on it. After the Surveyor left, the staff reminded the Director of Nursing that the Refrigerator Cleaning is done monthly and is documented on the Medication Refrigerator Temperature Log. The policies "PreOp/PACU Sanitation" will be reviewed with facility staff. The policy "Environment: Housekeeping Standards" will be revised to include a process ensuring that all high-touch surfaces are cleaned and/or disinfected, and a specific process for cleaning to ensure that all surfaces are cleaned in a manner to prevent contamination of previously disinfected surfaces. These policies and	10/09/2014	

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	<p>Refrigerator", no policy number, last approved on 6/19/14, indicated:</p> <p>a. Under "Procedure", it read in the last bullet point: "The medication refrigerator should be inspected monthly for cleanliness and cleaned as appropriate...".</p> <p>4. On 9/10/14 at 10:05 AM, while on tour of the pre op area in the company of staff member #55, the director of nursing, it was observed that the patient nutrition refrigerator had dust/debris on the bottom door shelf and the bottom refrigerator shelf.</p> <p>5. Interview with staff member #55 at 10:05 AM on 9/10/14 indicated:</p> <p>a. There may be confusion between facility staff and contracted cleaning staff as to who is to clean the refrigerator on a monthly basis, as per the policy.</p> <p>b. There is no documentation of monthly cleaning of the pre op refrigerator by either the nursing staff or the contracted cleaning staff.</p> <p>6. On 9/10/14 at 10:10 AM, while on tour of the pre/post op area in the company of staff member #55, the director of nursing, it was observed that:</p> <p>a. The medication refrigerator, under the counter, (located in the medication room) had a large accumulation of dust</p>		<p>processes will be reviewed with facility staff and housekeeping staff, as well as the Medical Advisory Committee and Governing Body. The Governing Body approved this revision. (b) (5) (A) 2. This will be prevented from recurring in the future by evaluation of the cleaning quarterly by the Director of Nursing or Infection Control Coordinator. The results of these evaluations will be shared with the facility and housekeeping staff, as well as, the Infection Control Committee, the Medical Advisory Committee and Governing Body. The facility and housekeeping staff will receive additional training if needed as a result of these evaluations. (b) (5) (A) 3. The Director of Nursing, the Infection Control Coordinator and the Governing Body are responsible.</p>				

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S001180	<p>on the top.</p> <p>b. The paper towel holder located in the medication room had a large accumulation of dust on the top.</p> <p>7. Interview with staff member #55 at 10:10 AM on 9/10/14 indicated the contracted cleaning staff are responsible for these areas and are not performing cleaning processes as expected by the facility.</p> <p>8. At 10:42 AM on 9/10/14, while on tour of the sub sterile room (between the two OR suites), in the company of staff member #55, the director of nursing, it was observed that:</p> <p>a. There was a large accumulation of dust on top of the blanket warmer.</p> <p>b. There was an accumulation of dust on the edge/shelf of the pass through window.</p> <p>9. Interview with staff member #55 at 10:42 AM on 9/10/14, indicated that nursing staff does the daily terminal cleaning of the surgical areas, the contracted housekeeping staff only does the monthly wall washing in this area.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE,</p>						

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410	<p>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 establish a safety management program that included a review of safety functions by a committee appointed by the chief executive officer and included representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. The policy/procedure Safety Management and Responsibility (approved 6-14) failed to indicate the safety committee membership requirements including representatives from administration and patient care services.</p> <p>2. On 9-08-14 at 1200 hours, staff A2 was requested to provide documentation of safety management committee minutes and none was provided prior to exit.</p> <p>3. The governing board minutes dated</p>	S001180	<p>(c) (1) 1. The policy "Safety Management and Responsibility" will be revised to indicate the safety committee membership requirements including representatives from administration and patient care services. Currently the Safety Committee meets during the Medical Advisory Committee and includes the Medical Director, the Administrator and the Director of Nursing. In the future a staff RN will be included in a Safety Committee meeting before the Medical Advisory Committee meeting. This policy will be reviewed with the facility staff, the Medical Advisory Committee and the Governing Body. The Governing Body approved this revision. (c) (1) 2. The deficiency, with respect to the policy, will not recur as policies will only be revised after review and approval by the Governing Body. (c) (1) 3. The Director of Nursing and the Governing Body are responsible.</p>	10/09/2014

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S001182	<p>12-18-13, 3-12-14 and 6-19-14 indicated that the meeting was attended by the medical director and governing board chairman MD11, the administrator A1 and the director of nursing A2. The minutes indicated that a subject heading 'E' titled Safety/Physical Environment was reviewed and no governing board documentation indicated that a representative of patient care services attended the governing board meetings</p> <p>4. During an interview on 9-10-14 at 1230 hours, the administrator A1 confirmed that the Safety Management and Responsibility policy failed to indicate the membership requirement to include a representative from patient care services, confirmed that the governing board minutes failed to indicate that a representative of patient care services attended the governing board meetings, and confirmed that confirmed that no other documentation of safety management committee meetings was available.</p> <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>						

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	<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, observation and interview, the center failed to develop and maintain its safety management program and failed to ensure that actions are taken to correct and improve center safety and to provide a safe environment for patients, personnel and the public.</p> <p>Findings:</p> <p>1. The policy/procedure Safety Management and Responsibility (approved 6-14) failed to indicate the safety program scope and committee responsibilities including a review of fire and disaster drills, emergency preparedness activities, safety-related surveillance and inspections, and monitoring of corrective actions for effectiveness if indicated. The policy/procedure indicated that hazard identification and corrective action would be included in the quarterly safety report to the Medical Advisory Committee (MAC) and no MAC meeting minutes dated 12-18-13, 3-12-14 or 6-19-14 indicated safety committee activity or indicated the review of a safety report.</p>	S001182	<p>(c) (2) 1. The policy "Safety Management and Responsibility" will be revised to indicate the safety program's scope and committee responsibilities including a review of fire and disaster drills, emergency preparedness activities, safety-related surveillance and inspections, and monitoring of corrective actions for effectiveness if indicated. The hazard identification and corrective action will be reviewed at the quarterly Medical Advisory Committee meeting per policy. This policy will be reviewed with the facility staff, the Medical Advisory Committee and the Governing Body. The Governing Body approved this revision. (c) (2) 2. The deficiency, with respect to the policy, will not recur as policies will only be revised after review and approval by the Governing Body. (c) (2) 3. The Director of Nursing and the Governing Body are responsible.</p>	10/09/2014

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	<p>2. The governing board minutes dated 3-12-14 and 6-19-14 indicated the following: "E. Safety/Physical Environment ...(i) Environmental Surveillance Report reviewed ... metal needs to get put on door going into patient corridor and doors to OR rooms need to get closers put on them ... maintenance was contacted to get this done ..." No governing board documentation dated 12-18-13, 3-12-14 or 6-19-14 indicated that a review of fire safety or disaster preparedness drills was performed.</p> <p>3. During a tour of the center on 9-09-14 at 1140 hours, the following condition was observed: no automatic door closer attached to the OR2 entrance door connecting with the common surgery corridor.</p> <p>4. During a tour of the center on 9-09-14 at 1150 hours, the following condition was observed: no automatic door closer attached to the OR1 entrance door connecting with the common surgery corridor.</p> <p>5. During a tour of the center on 9-09-14 at 1208 hours, the following condition was identified in the substerile central reprocessing room: three (3) disconnected automatic door closers were</p>			

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S001196	<p>observed on the 3 doors connecting with OR1, OR2, and the common surgery corridor.</p> <p>6. During an interview on 9-09-14 at 1208 hours, the director of nursing A2 confirmed that the door closer units needed to be repaired or replaced.</p> <p>7. During an interview on 9-10-14 at 1130 hours, the director of nursing A2 confirmed that the action indicated in the governing board minutes dated 3-12-14 and 6-19-14 to install door closer units on the OR1 or OR2 entrance doors had not been performed.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAc 15-2.5-7(c)(5)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(5) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with center policy and state and local regulations.</p> <p>Based upon document review and interview, the center lacked documentation of a periodic fire inspection by State and/or local fire control agencies.</p>	S001196	(c) (5) 1. The Director of Nursing contacted the Elkhart Fire Department Inspector to do a Fire Code Inspection. The Fire Code Inspection was done on 10/2/2014. The documentation	10/02/2014

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	<p>Findings:</p> <ol style="list-style-type: none"> 1. On 9-08-14 at 1200 hours, the director of nursing A2 was requested to provide documentation of a recent fire inspection report by a State or local fire agency and none was provided prior to exit. 2. Center documentation indicated that the last local fire department inspection was completed on 3-21-12. 3. During an interview on 9-08-14 at 1305 hours, the director of nursing A2 indicated that they (A2) were not aware of a recent fire inspection. 4. During an interview on 9-10-14 at 1220 hours, the administrator A1 confirmed that no documentation of a recent fire inspection was available. 		<p>will be kept in the Director of Nursing's office. (c) (5) 2. The Director of Nursing will keep track of inspections due to prevent this from recurring in the future. The Elkhart Fire Department Inspector will be contacted if no inspection has occurred on a yearly basis. (c) (5) 3. The Director of Nursing is responsible.</p>				