

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001051	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 03/07/2013
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NAME OF PROVIDER OR SUPPLIER INDIANAPOLIS ENDOSCOPY CENTER LLP	STREET ADDRESS, CITY, STATE, ZIP CODE 8315 E 56TH ST STE 100 INDIANAPOLIS, IN 46216
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S000000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 007886</p> <p>Survey Date: 3/5/2013 & 3/7/2013</p> <p>Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor</p> <p>Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 03/12/13</p>	S000000		

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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S000010	<p>410 IAC 15-2.2-1 COMPLIANCE WITH RULES 410 IAC 15-2.2-1 (a)</p> <p>Sec.1.(a) All centers shall be licensed by the department and shall comply with applicable federal, state, and local laws and rules.</p> <p>Based on document review, the facility failed to comply with all applicable state laws for 4 of 4 unlicensed/non-certified Instrument Coordinator/Patient Technicians employee files that were reviewed (#15, 16, 17, and 18).</p> <p>Findings include:</p> <p>1. IC 16-28-13-4: a health care facility shall apply within three (3) business days from the date a person is employed as a nurse aide or other unlicensed employee for a copy of the person's state nurse aide registry report from the state department and a limited criminal history from the Indiana central repository for criminal history information under IC 5-2-5 or another source allowed by law.</p> <p>2. Instrument Coordinator/Patient</p>	S000010	<p>S 010 – Plan of Correction and Prevention 1-3. The employee files of the four (4) Instrument Coordinator/Patient Technicians have been updated to include the health care provider search from the Indiana Online Licensing website in accordance with IC 16-28-13-4. One of the employee files had this search in the Human Resources file (off site), since she was the only one (1) of the four (4) hired since the implementation of this State law. However, it was not in her employee file on site. This has since been changed and all four (4) Instrument Coordinator/Patient Technician employee files now contain this health care provider search (attached). Effective immediately, these files will be maintained as outlined in the <i>Professional License Verification</i> policy and the <i>Employee/Physician File Requirements</i> policy (attached) by the Director of Nursing. ADDENDUM ON 4/22/13: In an effort to prevent this from occurring in the future, any employee hired as an unlicensed/non-certified Instrument Coordinator/Patient</p>	04/03/2013	

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	<p>Technician's Job Description stated, "Assists with patient care Admit/Recovery Room; Some of these duties include, but are not limited to: Give patient drinks when ready, Discontinue IVs, Assist patients to bathroom and with dressing, Escort patients to cars, Assist with positioning patients."</p> <p>3. Review of staff members' #15, #16, #17, and #18 employee files indicated that their Human Resource files lacked documentation of a nurse aide registry report. The four Instrument Coordinator/Patient Technicians were not certified and provide direct patient care.</p>		<p>Technician will have a health care provider search from the Indiana Online Licensing website for Nurse Aid Registry performed as part of the pre-employment checklist by our Human Resources Department within three (3) days of employment. The responsible party for monitoring these employee files will be the Director of Nursing.</p>				

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S000432	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iii)</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>(iii) Cleaning, disinfection, and sterilization.</p> <p>Based on observation, policy and procedure review, manufacturer's directions, and interview, the infection control committee failed to ensure the patient care areas were cleaned according to policy to prevent cross-contamination between patients and failed to ensure the appropriate rinsing procedures for high level disinfection were followed in the instrument room.</p> <p>Findings included:</p> <p>1. At the completion of the case observation in procedure room 4 at 1:40 PM on 03/05/13, the cleaning procedure for room turnover was observed. Staff member #A19 used Cavicide XL wipes for surface disinfection, but failed to wipe the monitor, blood pressure, and oxygen saturation leads that had been</p>	S000432	<p>S 432 – Plan of Correction and Prevention 1-4. Regarding items 1-4 deficiencies, staff were re-educated on the infection control practices as outlined in the <i>Cleaning of Clinical Areas by Staff</i> policy in Staff Meeting dated March 21, 2013. Staff meeting minutes, policy, and attendance sheet are attached. In an effort to prevent deficiencies in these practices, the Clinical Coordinators will perform twenty (20) quarterly cleaning audits (attached), ten (10) in Patient Rooms and ten (10) in Procedure Rooms for twelve (12) months to monitor the cleaning of patient rooms and procedure rooms in between patients. This will include the appropriate use of Cavicide XL wipes and the required 3 (three) minute drying time. These audits will be presented to the Operations Committee and Governing Board meetings. This</p>	04/30/2013	

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	<p>disconnected from the patient and hung on the side of the equipment. The computer keyboard and writing shelf, that a nurse wearing gloves had been using while also helping to hold and position the patient, were not cleaned before another patient was brought into the room.</p> <p>2. At 1:55 PM on 03/05/13, the room turnover cleaning process was observed in the pre/post area. Staff member #A13 used the Cavicide XL wipes to clean the patient cart, took a clean sheet to fan the cart and hasten the drying process, and immediately remade the cart with clean linens. The process took approximately 1- 2 minutes. Staff member #A20 was in the room and assisting with the cleaning. At one point, staff member #A20 dropped the Cavicide XL wipe on the floor, picked it back up, and continued wiping the siderails of the patient cart. Neither staff member cleaned the chairs in the room.</p> <p>3. The facility policy "Cleaning of Clinical Areas by Staff", last reviewed 05/23/11, indicated, "Patient Rooms: These areas/items will be thoroughly leaned with a hospital grade disinfectant following manufacturer's instructions for use. A. Between each patient: ...blood pressure cuff, EKG cord, reusable oximeter clip, monitor cords, visitor chair.</p>		<p>process will be implemented April, 2013 (2 nd quarter 2013). At the completion of the twelve (12) months, the Director of Nursing will assess the need for ongoing Cleaning Audits based on trend analysis. 5-9. The following policies have been revised to include manufacturer's recommendations of rinsing with use of Cidex OPA: <i>Cidex OPA Use and Testing; Processing Water Bottles and Water Caps; Cleaning of Endoscopes – (Detailed)</i> as attached. An inservice was performed on all staff responsible for these practices on 3/27/13 (sign up sheet attached). Policy revisions include: "Following removal from high level disinfectant, thoroughly rinse the water bottles and accessories by immersing completely in a large volume (e.g. 2 gallons) of water. Use sterile water unless potable water is acceptable; completely immerse the water bottles/accessories in the water for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer; manually flush all lumens using correct attachments with large volumes (not less than 100ml) of rinse water unless otherwise noted by manufacturer; discard the rinse water; always use fresh volumes of water for each rinse; do not reuse water for rinsing or any other purpose; repeat the procedure TWO (2) additional</p>		

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	<p>...Procedure Rooms: A. Between each patient case: ...All high touch areas included, but not limited to, light switch plates, door handles/plates, keyboards, mouse, wrist rests, monitor cords."</p> <p>4. The manufacturer's label on the Cavicide XL wipes indicated surfaces wiped with the disinfectant needed to remain visibly wet for 3 minutes for appropriate effectiveness against the various organisms.</p> <p>5. During the tour of the facility at 2:15 PM on 03/05/13, accompanied by staff member #A4, a basin of Cidex OPA for high level disinfection was observed in the instrument room. Staff member #A15 indicated dilators, guidewires, and endo water bottles were soaked in the solution for 12 minutes, then rinsed under tap water in the nearby sink. He/she indicated sterile water was used if needed, then the items were dried. He/she did not describe any specific three separate rinsing procedures when questioned.</p> <p>6. The facility policies "Cidex OPA Use and Testing" and "High Level Disinfectant", last reviewed 11/16/11, described the soaking and testing procedures, but did not discuss any rinsing procedures.</p>		<p>times, for a total of THREE (3) rinses, with large volumes of fresh water to remove the disinfectant residues." To monitor on an ongoing basis, this will be added to the annual competencies for relevant personnel by the Infection Preventionist. ADDENDUM ON 4/22/13: The responsible party for monitoring and evaluating the above mentioned practice implementations will be the Infection Preventionist.</p>				

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	<p>7. The facility policy "Processing Water Bottles and Water Caps", last reviewed 11/16/11, indicated, "7. After disinfection, thoroughly rinse the container, lid, outside of tubing and O ring with tap water followed with 70% alcohol."</p> <p>8. The manufacturer's directions for Cidex OPA indicated, "B. Rinsing Procedure: Following removal from Cidex OPA Solution, thoroughly rinse the medical device by immersing it completely in a large volume (e.g. 2 gallons) of water. Use sterile water unless potable water is acceptable. Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer. Manually flush all lumens with large volumes (not less than 100 milliliters) of rinse water unless otherwise noted by the device manufacturer. Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove Cidex OPA Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME</p>			

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	<p>WATER IMMERSION RINSES ARE REQUIRED."</p> <p>9. At 2:00 PM on 03/07/13, staff member #A4 confirmed the facility policies did not address the 3 separate rinses after soaking in Cidex OPA as specified by the manufacturer. He/she also indicated the breeches in the cleaning procedures observed were not according to facility standards or expectations.</p>				

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S000706	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(2)</p> <p>The medical staff shall do the following:</p> <p>(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with center policy and applicable state and federal law.</p> <p>Based on documentation review and staff interview, the facility failed to provide evidence of current competency on Conscious Sedation for 5 of 5 credentialed physicians (#5, 6, 7, 8, and 9).</p> <p>Findings included:</p> <p>1. Employee/Physician File Requirements policy (last approved 9/25/2012) stated, "A personnel file will be maintained on each employee, whether part of full-time, and will be reviewed annually. A list of essential documents kept in the file will be kept on the folder inside cover. Organization of file for Physician: Medical Staff Application and</p>	S000706	<p>S 706 – Plan of Correction and Prevention</p> <p>1-9. The <i>Employee/Physician File Requirements</i> policy (attached) has been revised to reflect that the <i>Statement of Conscious Sedation (attached)</i> will validate competency in conscious sedation by ongoing and on the job training based on the quantity of cases performed over a 2 (two) year period for each physician. The <i>Statement of Conscious Sedation</i> will be updated with the reappointment process in credentialing every two (2) years. This will be implemented at the next Governing Body meeting on May 15, 2013. The Director of Nursing will be responsible for maintaining these files on an ongoing basis.</p>	05/15/2013	

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	<p>Reappointments, Valid License, Valid Board Certification, Statement of Conscious Sedation, Letter delineating privileges and approval by the Medical Staff, ..."</p> <p>2. Medical Staff Bylaws of Indianapolis Endoscopy Center LLP (last approved November 16, 2011) stated, "The clinical privileges recommended to the Governing Body will be based upon the applicant's education, training, experience, demonstrated competence and judgement, references, and other relevant information.</p> <p>3. Physician staff member #5 was licensed as Gastroenterology and Internal Medicine and initially appointed 9/3/04. The staff member did not evidence any Statement of Conscious Sedation. However, the staff member had a Sedation & Analgesia Competency test from 2/20/2004.</p> <p>4. Physician staff member #6 was</p>			

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	<p>licensed as Gastroenterology and Internal Medicine and initially appointed in 8/1/04. The staff member had a Statement of Conscious Sedation. However, the statement was only one in the physician's credential file and contained no date when it was signed.</p> <p>5. Physician staff member #7 was licensed as Gastroenterology and Internal Medicine and initially appointed in 8/1/04. The staff member had a Statement of Conscious Sedation. However, the statement was only one in the physician's credential file and contained no date when it was signed.</p> <p>6. Physician staff member #8 was licensed as Gastroenterology and Internal Medicine and initially appointed in 1/5/00. The staff member had a Statement of Conscious Sedation. However, the statement was only one in the physician's credential file and</p>						

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	<p>contained no date when it was signed.</p> <p>7. Physician staff member #9 was licensed as Gastroenterology and Internal Medicine and initially appointed in 7/2/01. The staff member had a Statement of Conscious Sedation. However, the statement was only one in the physician's credential file and contained no date when it was signed.</p> <p>8. The Statement of Conscious Sedation had a different address than the Indianapolis Endoscopy Center currently resides. The statement for the 5 physicians read exactly the same. The statement stated, "Dr. XXXXXX, having performed over 1000 conscious sedation procedures at Community Hospitals Indianapolis, without quality issues, is credentialed to administer conscious sedation at Indianapolis Endoscopy Center."</p> <p>9. At 12:15 PM on 3/7/13, staff</p>				

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	member #2 confirmed there was no date on the Statement of Conscious Sedation to reveal if the statement was current or not. The staff member indicated the facility does not have Anesthesiologists or CRNAs. The staff member indicated the facility requires the Register Nurses to be trained in administering medication for Conscious Sedation; therefore, the physician files should have evidence of competency in ordering medication for constant sedation.			