STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	15C0001028	A. BUILDING 00 B. WING	08/22/2019

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GASTROINTESTINAL ENDOSCOPY CENTER	801 ST MARYS DR, STE 110 W EVANSVILLE, IN 47714

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S 0000 Bldg. 00	This visit was for a state licensure survey of an ambulatory surgery center. Facility Number: 005820 Survey Dates: 8/21/19 to 8/22/19 QA: 9/12/19	S 0000	No update. Description only	
S 0010 Bldg. 00	410 IAC 15-2.2-1 COMPLIANCE WITH RULES 410 IAC 15-2.2-1 (a) Sec.1.(a) All centers shall be licensed by the department and shall comply with applicable federal, state, and local laws and rules. Based on document review and interview, the facility failed to comply with a Indiana State Code, requiring Nurse Aide Registry checks of Nurse Aides and other non-licensed Employees, for 2 of 15 personnel files (staff #N3 and #N11). Findings include: 1. Indiana Code IC 16-28-13-4 indicates Operator of health care facility; request for nurse aide registry report and limited criminal history report: Sec. 4. (a.) operates or administers a	S 0010	**1. How are you going to correct the deficiency? If already corrected, include the steps taken and the date of correction.** Employees that do not have a license were identified and a search was conducted on the CNA Registry to see if a record existed. The findings were then documented and placed in the employee's file in the CNA Registry folder. (See Document CNA Registry Check) **2. How are you going to prevent the deficiency from recurring in the future?** The CNA Registry is a part of our list of items that ISDH requires our employees to have in their file.	09/27/2019

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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	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 under IC 10-13-3 or other source allowed by law. 2. Review of staff personnel files #N3 and #N11, Unlicensed Technicians, indicated #N3 was hired on 4/23/2012, and #N11 was hired on 4/17/2017, and both lacked documentation of a Nurse Aide Registry check. 3. On 8/22/2019, at approximately 1500 hours, staff member #A8, Human Resource Manager, indicated in interview that they had not done Nurse Aide Registry checks and did not know that they needed to to do them.		This has been added to the New Hire Documentation requirements. **3. Who is going to be responsible for numbers 1 and 2 above; i.e., director, supervisor, etc.?**Human Resources Manager and Director of Endoscopy **4. By what date are you going to have the deficiency corrected?** Date of correction was 9/27/2019	
S 0230	410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND			

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Bldg. 00	DUTIES 410 IAC 15-2.4-1(e)(5) The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following: (5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility. Based on document review and interview, the Governing Body (GB) failed to provide for periodic review of the center and its operation by a utilization review (UR) or other committee composed of 3 or more physicians having no financial interest in the facility for the past 4 quarters. Findings include: 1. Policy/Procedure review: A. Review of the policy titled Utilization Review Program Description, approved 6/2018, indicated the following: Committee Structure: The committee consists of the following persons; including, but not limited to: At least three (3) duly licensed physicians having no financial interest in the facility. B. Review of Medical Staff By-Laws, Rules and Regulations,	S 0230	**1. How are you going to correct the deficiency? The Utilization Review Program Description (attached) was revised to adjust the requirement ensuring that "At least three (3) duly licensed physicians having no financial interest in the facility". This description was approved by the Governing Body on 9/23/19. Subsequently, we have contracted a third UR MD reviewer who will start with Quarter 3 of 2019.** **2. How are you going to prevent the deficiency from recurring in the future? Standing agenda template for the Quality and Safety Committee has been revised to read "Utilization Review Report (at least 3 MD's participating)". This will ensure that the Quality Committee and the**	09/23/2019

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	Reviewed/Revised 11/2017, indicated the following: Article III. Section B. Utilization Review Committee: The Utilization Review Committee shall consist of three peer review physicians who are not members of the (Center) Medical Staff and who have no financial interest in the center. 2. Review of facility documents lacked evidence of UR meeting minutes by an appropriate UR or other committee within the past 4 quarters. 3. On 8/22/19, between approximately 10:00 a.m. and 11:00 a.m., A5, Quality Manager, indicated the center had only 2 physicians on their UR committee and did not have 3 non-owner physicians serving on the committee. A5 indicated that the GB and Medical Staff (MS) had recently decided that only 2 physicians were needed and approved to change the bylaws. A5 verified that the center did not have UR committee minutes, only individual physician review of medical records. 4. On 8/22/19, between approximately 11:00 a.m. and 12:00 p.m., A3, Chief Operating Officer, verified that the center did not have a UR committee composed of 3 or more physicians having no financial interest in the facility.		**Medical Director have at least a quarterly report to ensure this is happening according to standards. (See Standing Agenda)** **3. Who is going to be responsible for numbers 1 and 2 above; i.e., director, supervisor, etc.? Quality Manager and Medical Director.** **4. By what date are you going to have the deficiency corrected? 9/23/19**	

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S 0400 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(a) (a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors. Based on document review, observation and interview, the facility failed to provide a safe and healthful environment in 15 instances during the survey. Findings include: 1. Facility Policy titled Daily Cleaning Protocol, last revised 11/5/2017, (no number), indicated: To provide a safe, clean environment for each patient and staff member. Procedure Rooms: Terminal Room Cleaning after last patient of the day - Wipe all flat surfaces with a germicidal wipe, wipe all equipment in each room with appropriate cleaning wipe; this includes but is not	S 0400	**How are you going to correct the deficiency? If already corrected, include the steps taken and the date of correction.** 1. Optimal storage of endoscopes in the storage cabinets to facilitate drying will be corrected October 9th. Contractors have been to the facility to look at the storage cabinets and have decided that the part that holds the scopes will have to be raised 1.5 inches. This will prevent the endoscope tips from touching the bottom of the cabinet. 2. Responsibility for this action lies with the Lead Technician and Infection Control Nurse. 3. The clean storage room which had dust and debris on the	10/09/2019

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	limited to vital signs monitor, phone, stools, anesthetist carts, computer and table. 2. Cleaning Specifications listed with contracted daily services, 10/3/2016, indicated: Operating Room (OR) Area/ Procedure Room; daily-damp dust mop, disinfect all horizontal surfaces. 3. Olympus Endoscope Manufacturing Standards for Reprocessing Flexible Video Endoscopes/Esophageal Ultra Sound (EUS) Scopes: (After processing) thoroughly dry all parts of the endoscope. Endoscopes should be stored in a clean, dry and well ventilated area to minimize the possibility of recontamination. 4. Association of Operating Room Nurses (AORN) Guidelines for flexible endoscopes indicated: The collective evidence shows that optimal storage of flexible endoscopes facilitates drying, decreases the potential for contamination. 5. On tour of facility Operating Rooms and Post Anesthesia Care Unit (PACU) on 8/22/2019 at approximately 1115 hours, accompanied by staff #A2, Registered Nurse (RN) OR Manager, and during the observation of a patient procedure on 8/22/2019 at approximately 1200 hours, the following issues were		floor has been corrected and cleaned September 16, 2019 by housekeeping. To prevent this deficiency from occurring in the future, staff was sent an email September 27, 2019 that cleaning of this room will be added to the End of Day Sheets and will be mentioned again in the next staff meeting in October. This form will be changed and put in place on October 9th. 4. The OR rooms with dust on EUS machine, back of anesthesia cart, endoscope cart, and glove dispensing box has been corrected and cleaned on September 27, 2019. Staff was sent an email September 27, 2019 reminding them to clean all equipment as stated in our Daily Cleaning Protocol Policy. This will be mentioned again in our next staff meeting in October. 5. The OR rooms with dust around the edges and in corners has been corrected and cleaned on September 16, 2019. An Endoscopy Weekly Walk-Through sheet to monitor housekeeping has been created by Infection Control Nurse. (See attached form) This weekly task will be started October 4, 2019 and performed by Infection Control Nurse and/or GEC Manager. When this walk-through is initiated, IC RN and GEC Manager will make sure housekeeping has cleaned general and specific areas mentioned that need cleaned	

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	noted: A. PACU: Clean storage room had gray dust and debris on floor. Layer of gray dust on sharps containers in bays 1B, 1C, 1D (the three rooms observed). B. OR rooms 3 and 4 were observed. It was noted that EUS machine and cart, back of anesthesia cart, endoscope cart and glove dispensing box in room 4 were covered with gray dust. In both rooms 3 and 4 it was noted that the floors had dust around the edges and in corners. C. The floors in autoclave processing area had gray dust on floor, with corners having the most. D. Endoscope storage cabinet was observed to be storing 4 scopes. All 4 had the tips resting on towels on the floor of the cabinet, preventing complete drying. 6. In interview, on 8/22/2019 at approximately 1150 hours, staff member #A2 indicated agreement with the above findings and indicated that they are in the process of trying to improve cleaning service processes, possibly switching to another company. Thought there were hooks for the scopes high enough that they would not touch the bottom of storage cabinets.		weekly such as backs of anesthesia carts, glove holders, and the back of the EUS machine. 6. The autoclave room which had dust on the floor will be corrected and cleaned September 27, 2019. To prevent this deficiency from occurring in the future, this task will be added to the End of Day Sheets and staff will be sent an email September 27, 2019 to let them be aware of this change. This will be mentioned again in the next staff meeting in October.	
S 0404 Bldg. 00	410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(b)			

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	(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers. Based on document review and interview, the facility failed to have a program to identify possible tuberculosis (TB) infections via annual Purified Protein Derivative (PPD) skin testing for 11 of 15 staff personnel files reviewed (#N2-N7, N9, N10-N12 and N14). Findings include: 1. Employee Policy Manual, #501, Safety, (no date) indicated: requires annual PPD skin testing for all Endoscopy Center clinical staff. 2. Review of personnel files for 15 clinical staff indicated that staff members #N2-N7, N9, N10-N12 and N14 had not had a PPD test since hire, nor had they signed a waiver indicating that they had not been exposed or refusal to do so. 3. On 8/22/2019, at approximately 1430 hours, staff member #A2, Registered Nurse (RN), Operating Room Manager,	S 0404	1. This has been corrected, on September 27, 2019 Employee Policy #501 has been updated to state that "DCE requires an annual TB risk assessment tool be completed by all clinical, physician, nurse practitioner, and endoscopy center staff. However, since DCE is considered a low risk facility for contracting TB, staff working in other areas of DCE may choose to decline to complete the TB risk assessment tool. If an exposure occurs, the employees exposed will be tested." (See attached TB Program Policy 501). This is in line with the CDC requirements for Low Risk Facilities. 2. Responsibility for the TB Program lies with Infection Control Nurse, Director of Endoscopy, and Human Resources.	09/27/2019

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	indicated in interview that they had not done annual PPDs or waivers because they thought they were in a low risk area and did not need to.			
S 0744 Bldg. 00	410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(D) These bylaws and rules must be as follows: (3) Include, at a minimum, the following: (D) A procedure for designating an individual practitioner with current privileges as chief, president, or chairperson of the staff. Based on document review and interview, the Medical Staff (MS) failed to adopt bylaws that included a procedure for designating an individual practitioner with current privileges as chief, president or chairperson of the MS. Findings include: 1. Review of the Medical Staff By-Laws, Rules and Regulations, reviewed/revised 11/2017, indicated that the "President of the Governing Body" shall mean the governing director of the facility and the	S 0744	**1. How are you going to correct the deficiency? The Governing Body and Medical Staff By Laws were both revised, presented and approved (9/23/19) to include a description of the Medical director role, how the Medical Director is elected and their responsibilities. Also on 9/23/19 the Governing Body approved the Medical Director under this description.** **2. How are you going to prevent the deficiency from recurring in the future? By Law deficiency that has now been**	09/23/2019

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	ultimate authority. He/she also shall act as Medical Director and Executive Officer of the Center. The bylaws lacked documentation of a procedure for designating an individual practitioner with current privileges as chief, president or chairperson of the medical staff. 2. On 8/22/19, between approximately 1:45 p.m. and 3:15 p.m., A3, Chief Operating Officer, verified that the MS By-Laws lacked documentation of a procedure for designating an individual practitioner with current privileges as chief, president or chairperson of the medical staff.		**corrected.** **3. Who is going to be responsible for numbers 1 and 2 above; i.e., director, supervisor, etc.? Administrator** **4. By what date are you going to have the deficiency corrected?** Date of correction was 9/23/2019	
S 0746 Bldg. 00	410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(E) These bylaws and rules must be as follows: (3) Include, at a minimum, the following: (E) A statement of duties and privileges for each category of the medical staff. Based on document review and interview, the Medical Staff (MS) failed to ensure that the MS bylaws included a statement of duties and privileges for each category of the medical staff for one center.	S 0746	**1. How are you going to correct the deficiency? If already corrected, include the steps taken and the date of correction. The Medical Staff and Governing Body By Laws (MS Article II Section A see**	09/23/2019

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	Findings include: 1. Review of Medical Staff By-Laws, Rules and Regulations, Reviewed/Revised 11/2017, indicated the following: Article II. Section B. Medical and Allied Health Staff Membership Qualifications: The category assigned to staff membership to (The Center) is active. The bylaws lacked documentation of duties and privileges for the category of "Active Staff". The Bylaws also lacked documentation of category for locum physician's and/or allied health. 2. Review of minutes titled "Governing Body and Medical Staff Meeting Minutes" indicated that on 7/16/18, the committee(s) discussed "Upcoming Locum Dates" of which locum's would be working in the facility. The minutes indicated Surgeon MD9 would be working August 6-10 and Surgeon MD10 had no scheduled dates from July forward. 3. Review of procedure lists for 2018 and 2019 indicated that MD9 performed procedures at the Center during August of 2018 and that MD10 performed procedures at the Center during June of		**attached) was revised, presented and approved (9/23/19) by the Governing Body to define the following categories for Medical Staff: Full Time, Part Time (PRN), Locum and Courtesy. The applications for both initial appointment as well reappointment (also attached) have been revised to include a selection for the applicant to choose which category they are applying for.** **2. How are you going to prevent the deficiency from recurring in the future? By Law and application permanent change.** **3. Who is going to be responsible for numbers 1 and 2 above; i.e., director, supervisor, etc.? Administrator and Billing Manager** **4. By what date are you going to have the deficiency corrected?** Date of correction was 9/23/2019	

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	2018. 4. On 8/22/19, between approximately 1:45 p.m. and 3:15 p.m., A3, Chief Operating Officer, verified that the MS did utilize locum staff for both Surgeons and Allied Health Staff. A3 also verified that the MS By-Laws lacked documentation for locum staff, indicated all staff were in the category of "Active Staff" and lacked inclusion of a statement of duties and privileges for categories of the MS. A3 further indicated that Physician MS and Allied Health MS did not perform like duties of the staff, nor did they have like privileges.			