STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	15C0001065	A. BUILDING _____ B. WING _____	01/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SURGERY CENTER THE	7900 W JEFFERSON BOULEVARD, SUITE 102 FORT WAYNE, IN 46804

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 000	INITIAL COMMENTS The visit was for a Federal Re-certification survey and a Focused Infection Control survey. Facility Number: 009566 Survey Date: 1/11-14/2021 and 1/26/2021	Q 000		
Q 100	QA: 1/26/21 and 2/3/21 ENVIRONMENT CFR(s): 416.44 The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. This CONDITION is not met as evidenced by: Based on records review, observation, and interview; the facility failed to ensure annual inspection and testing of 5 of 5 fire door assemblies were completed in accordance of LSC 21.1.1.4.1. communicating openings in dividing fire barriers required by 21.1.1.4.1 shall be permitted only in corridors and shall be protected by approved self-closing fire door assemblies (see tag K761), failed to ensure 2 of 2 operating rooms (OR) contained either isolated power or ground-fault circuit interrupters (GFCI), unless otherwise determined by a risk assessment conducted by the facility governing body (see tag K913), and failed to ensure 1 of 2 Operating Rooms (OR) used flexible cords power strips powering medical equipment that met the required UL rating of 1363A or 60601-1 (see tag K920).	Q 100		2/26/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/18/2021

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Q 100	Continued From page 1 The cumulative effect of these systemic problems resulted in the facility's inability to ensure it had implemented a systemic plan of correction to prevent recurrence, therefore failing to ensure the provision of quality health care in a safe environment.	Q 100		
Q 101	PHYSICIAL ENVIRONMENT CFR(s): 416.44(a)(1) The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure 2 of 2 operating rooms (OR) contained either isolated power or ground-fault circuit interrupters (GFCI), unless otherwise determined by a risk assessment conducted by the facility governing body. This deficient practice could affect all patients in the event of an emergency in the facility's 2 ORs. Findings include: Based on observation with the Surgery Center Director on 01/26/21 between 12:13 p.m. and 12:35 p.m., the receptacles in the two operating rooms were not protected with isolated power or GFCIs. Based on record review with the Surgery Center Director at 11:00 a.m., no documentation of a risk assessment conducted by the facility governing body was available for review. Based on interview at the time of record review and	Q 101		2/5/21

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Q 101	Continued From page 2 observation, the Surgery Center Director stated no receptacles in the operating rooms contained isolated power or GFCIs, and a risk assessment for the ORs could not be found. The finding was review with the Surgery Center Director during the exit conference.	Q 101		
Q 104	SAFETY FROM FIRE CFR(s): 416.44(b)(1)-(3) (b) Standard: Safety from fire. (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4). (2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients. (3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC. This STANDARD is not met as evidenced by: Based on observation, records review, and interview; the facility failed to ensure annual inspection and testing of 5 of 5 fire door assemblies were completed in accordance of LSC 21.1.1.4.1. communicating openings in	Q 104		

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Q 104	Continued From page 3	Q 104		

dividing fire barriers required by 21.1.1.4.1 shall be permitted only in corridors and shall be protected by approved self-closing fire door assemblies. (See also Section 8.3.) LSC 8.3.3.1 Openings required to have a fire protection rating by Table 8.3.4.2 shall be protected by approved, listed, labeled fire door assemblies and fire window assemblies and their accompanying hardware, including all frames, closing devices, anchorage, and sills in accordance with the requirements of NFPA 80, Standard for Fire Doors and Other Opening Protectives, except as otherwise specified in this Code. NFPA 80 5.2.1 states fire door assemblies shall be inspected and tested not less than annually, and a written record of the inspection shall be signed and kept for inspection by the AHJ. NFPA 80, 5.2.4.1 states fire door assemblies shall be visually inspected from both sides to assess the overall condition of door assembly. NFPA 80, 5.2.4.2 states as a minimum, the following items shall be verified:
(1) No open holes or breaks exist in surfaces of either the door or frame.
(2) Glazing, vision light frames, and glazing beads are intact and securely fastened in place, if so equipped.
(3) The door, frame, hinges, hardware, and noncombustible threshold are secured, aligned, and in working order with no visible signs of damage.
(4) No parts are missing or broken.
(5) Door clearances do not exceed clearances listed in 4.8.4 and 6.3.1.7.
(6) The self-closing device is operational; that is, the active door completely closes when operated from the full open position.
(7) If a coordinator is installed, the inactive leaf closes before the active leaf.

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Q 104	Continued From page 4 (8) Latching hardware operates and secures the door when it is in the closed position. (9) Auxiliary hardware items that interfere or prohibit operation are not installed on the door or frame. (10) No field modifications to the door assembly have been performed that void the label. (11) Gasketing and edge seals, where required, are inspected to verify their presence and integrity. This deficient practice could affect all building occupants. Findings include: During records review with the Surgery Center Director on 01/26/21 at 11:13 a.m., no documentation of an annual inspection for the five fire door assemblies was available for review. Based on observation during the tour between 12:00 p.m. and 1:00 p.m., there were (4) 90-minute fire door assembly in the one-hour fire barrier and one fire door in the stairwell fire barrier. Based on interview at the time of records review and observation, the Surgery Center Director stated an annual fire door inspection for the five fire doors has not completed within the last year. The finding was review with the Surgery Center Director during the exit conference.	Q 104		
Q 108	BUILDING SAFETY CFR(s): 416.44(c) (c) Standard: Building Safety. Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health	Q 108		2/5/21

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Q 108	Continued From page 5 Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6). (1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC. (2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to ensure 1 of 2 Operating Rooms (OR) used flexible cords power strips powering medical equipment that met the required UL rating of 1363A or 60601-1. This deficient practice could affect one patient in OR #2. Findings include: Based on observation with the Surgery Center Director on 01/26/21 at 12:00 p.m., in OR #2 there was a power strip that did not meet 1363A or 60601-1 laying in the middle of the floor powering medical equipment that was in use. Based on interview at the time of observation, the Surgery Center Director agreed a power-strip was used to power medical equipment in OR #2 that did not meet 1363A or 60601-1. The finding was review with the Surgery Center Director during the exit conference.	Q 108		
Q 232	SAFETY	Q 232		2/10/21

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Q 232	Continued From page 6 CFR(s): 416.50(f)(2) [The patient has the right to -] (2) Receive care in a safe setting This STANDARD is not met as evidenced by: Based on document review, observation and interview, the center failed to ensure each patient and/or the patient's representative were informed of the patient's right to receive care in a safe setting for one facility. Findings include: 1. Review of the policy/procedure Patient Rights (reviewed 9-20) and the Notice of Patient Rights (revised 10-18) provided to the patient and/or the patient's representative lacked documentation indicating the right to receive care in a safe setting. 2. On 1-14-21 at 1420 hours, the posted Notice of Patient Rights (revised 10-18) on display in the patient waiting room was observed to lack documentation indicating the right to receive care in a safe setting. 3. On 1-14-21 at 1545 hours, the Chief Executive Officer A1 confirmed the above.	Q 232		
Q 233	SAFETY - ABUSE/HARASSMENT CFR(s): 416.50(f)(3) [The patient has the right to -] (3) Be free from all forms of abuse or harassment This STANDARD is not met as evidenced by: Based on document review, observation and interview, the center failed to ensure each patient	Q 233		2/10/21

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Q 233	Continued From page 7 and/or the patient's representative were informed of the right to be free from all forms of abuse, neglect or harassment for one facility. Findings include: 1. Review of the Notice of Patient Rights (revised 10-18) provided to the patient and/or the patient's representative lacked documentation indicating the right to be free from all forms of abuse, neglect or harassment. 2. On 1-14-21 at 1420 hours, the posted Notice of Patient Rights (revised 10-18) on display in the patient waiting room was observed to lack documentation indicating the right to be free from all forms of abuse, neglect or harassment. 3. On 1-14-21 at 1545 hours, the Chief Executive Officer A1 confirmed the above.	Q 233		
Q 241	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on document review, observation and interview, the facility failed to ensure the pre-operative area, an operating room, post-operative area/pantry were cleaned per policy for 1 of 1 pre-operative area, 1 of 2 operating rooms, 1 of 1 post-operative area/PACU [Post anesthesia Care Unit]/pantry.	Q 241		2/26/21

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Q 241	Continued From page 8 Findings include: 1. A facility policy titled "Environmental Cleaning" was last reviewed/revised on 10/2020 and indicated the following: "...PURPOSE: To provide patients with a clean, safe environment...commitment to reducing risk of infection through the reduction of microorganisms present. II. POLICY: Environmental cleaning and disinfection is a team effort involving surgical personnel and environmental services personnel. A. Terminal Cleaning and disinfection of operating and invasive procedures rooms is performed *When the scheduled procedures are completed for the day...*Each 24-hour period during the regular work week. B. All areas and equipment in the surgical practice setting are cleaned according to an establish[ed] schedule...Contracted Environmental Cleaning Responsibilities: Terminal Cleaning and Disinfecting: WHEN: Monday-Friday (2nd shift)...2. Sanitize/Spot Cleaning: A. Sanitize any soil or blood splatters on the wall and/or ceiling with approved solution. Pay special attention to the area around...telephones...B. Thoroughly damp wipe in a high to low sequence with an EPA [Environmental Protection Agency] registered disinfectant solution, ledges, shelving, cabinets, monitors...Preop [Preoperative]/PACU Personnel Responsibilities...Patient care bays/areas and associated receptacles are cleaned between patient use..." 2. Observations on tour of the facility on 1/13/21 beginning at 1:15 p.m. with N5 (Registered Nurse/Director) indicated the following: (A) An accumulation of dust on the top of the wall mounted sharps containers, on top of the cardiac	Q 241		

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Q 241	Continued From page 9	Q 241		

monitors and on top of the wall mounted cardiac monitor brackets. (Pre-operative area)
(B) An accumulation of dust on the top and back of the wall mounted telephone and the back of the wall mounted computer monitor. (Operating Room #1)
(C) An accumulation of dust on top of the ice/water dispensing machine. (PACU pantry)
(D) A heavy accumulation of dust on top of the back-wall ledge and on top of the wall mounted sharps container. (PACU bay #7)
(E) An accumulation of dust on the top of the cardiac monitor and on top of the sharps container. (PACU bay #6) (F) An accumulation of dust on top of the blanket warmer. (PACU)
(G) A heavy accumulation of dust on the back wall and the three black wall mounted clocks (PACU bays #1, 2 and 3)
(H) A heavy accumulation of dust on the back-wall ledge. (PACU bay #1)
(I) An accumulation of dust on the top and back of the wall mounted telephone and the back of the wall mounted computer monitor. (Operating Room #1)

3. A review of the current contracted environmental cleaning company schedule indicated the following: ...Pre/Post OP [Preoperative/Post-operative]/PACU areas...4. Dust all high and low areas...weekly..."

4. During an interview with N4 (Registered Nurse/Infection Control Preventionist) and N5 on 1/14/21 at 3:56 p.m., they verified the accumulation of dust as indicated above and the cleaning of those areas would be the responsibility of the contracted cleaning company staff.