

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 05/15/2024  
FORM APPROVED  
OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  155274		X2) MULTIPLE CONSTRUCTION A. BUILDING      -- B. WING            _____		X3) DATE SURVEY COMPLETED 04/29/2024	
NAME OF PROVIDER OR SUPPLIER  WATERS OF ROCKPORT SKILLED NURSING FACILITY, THE				STREET ADDRESS, CITY, STATE, ZIP COD 815 W WASHINGTON ST ROCKPORT, IN 47635			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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
E 0000  Bldg. --	<p>An Emergency Preparedness Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 483.73.</p> <p>Survey Date: 04/29/24</p> <p>Facility Number: 000174 Provider Number: 155274 AIM Number: 100274810</p> <p>At this Emergency Preparedness survey, The Waters of Rockport Skilled Nursing Facility was found in substantial compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 483.73</p> <p>The facility has 60 certified beds. At the time of the survey, the census was 31.</p> <p>Quality Review completed on 05/02/24</p>			E 0000			
E 0041 SS=C Bldg. --	<p>482.15(e), 483.73(e), 485.625(e) Hospital CAH and LTC Emergency Power §482.15(e) Condition for Participation: (e) Emergency and standby power systems. The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1) (i) and (ii) of this section.</p> <p>§483.73(e), §485.625(e) (e) Emergency and standby power systems. The [LTC facility and the CAH] must implement emergency and standby power</p>						

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

TITLE

(X6) DATE

Natalie

Walker

05/10/2024

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 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 disclosed 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>systems based on the emergency plan set forth in paragraph (a) of this section.</p> <p>§482.15(e)(1), §483.73(e)(1), §485.625(e)(1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health 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), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.</p> <p>482.15(e)(2), §483.73(e)(2), §485.625(e)(2) Emergency generator inspection and testing. The [hospital, CAH and LTC facility] must implement the emergency power system inspection, testing, and [maintenance] requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.</p> <p>482.15(e)(3), §483.73(e)(3), §485.625(e)(3) Emergency generator fuel. [Hospitals, CAHs and LTC facilities] that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.</p> <p>*[For hospitals at §482.15(h), LTC at §483.73(g), and CAHs §485.625(g):] The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain</p>						

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	<p>the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a>. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.</p> <p>(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, <a href="http://www.nfpa.org">www.nfpa.org</a>, 1.617.770.3000.</p> <p>(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.</p> <p>(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.</p> <p>(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.</p> <p>(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.</p> <p>(v) TIA 12-5 to NFPA 99, issued August 1, 2013.</p> <p>(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.</p> <p>(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.</p> <p>(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.</p> <p>(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.</p> <p>(x) TIA 12-3 to NFPA 101, issued October 22, 2013.</p> <p>(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.</p>						

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	<p>(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009..</p> <p>Based on record review and interview, the facility failed to implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code in accordance with 42 CFR 483.73(e)(2).</p> <p>Based on record review and interview, the facility failed to ensure an annual fuel quality test was performed for 1 of 1 diesel powered generator. NFPA 99, Health Care Facilities Code, 2012 Edition Section 6.5.4.1.1.2 states Type 2 EES (Essential Electrical System) generator sets shall be inspected and tested in accordance with Section 6.4.4.1.1.3. Section 6.4.4.1.1.3 states maintenance shall be performed in accordance with NFPA 110, Standard for Emergency and Standby Power Systems, 2010 Edition, Chapter 8. NFPA 110, Section 8.3.8 states a fuel quality test shall be performed at least annually using tests approved by ASTM standards. This deficient practice could affect all residents, as well as staff and visitors.</p> <p>Findings include:</p> <p>Based on record review on 04/29/24 between 9:30 a.m. and 12:15 p.m. with the Maintenance Supervisor present, there was documentation of an annual generator inspection/service dated 08/22/23, and a semi-annual generator inspection/service dated 02/21/24, however, there was no documentation of an annual fuel quality test for the diesel generator available for review during the past 12 month period. Based on interview at the time of record</p>			E 0041	<p><b>E041</b>– It is the intent of the facility to ensure to implement the emergency power system inspection, testing and maintenance requirements found in the Health Care Facilities Code, NFPA 110 and Life Safety Code in accordance with 42 CFR 483.73(e) (2) to meet set standards.</p> <p><b>1 CORRECTIVE ACTIONS TAKEN:</b></p> <p>a On May 10, 2024, the Maintenance Supervisor obtained a copy of the annual fuel quality test for the diesel generator from the 2/21/24 semiannual inspection/service and documented the results in the facilities Life Safety Binder to meet set standards. The Administrator verified the work on May 10, 2024.</p> <p><b>1 ALL OTHERS WITH POTENTIAL TO BE AFFECTED:</b></p> <p>a All residents and all staff and visitors have the potential to be affected but none were.</p> <p><b>2 MEASURES TO PREVENT REOCCURRENCE:</b></p> <p>a On May 8, 2024, the Administrator inserviced the Maintenance Supervisor/designee on the requirement that an annual fuel quality test for the emergency generator must be conducted and documented in the facilities Life</p>		05/27/2024

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K 0000	<p>review, the Maintenance Supervisor said a diesel fuel sample was taken during the 02/21/24 semi-annual inspection/service of the generator by the facility's vendor, however, the facility has not been sent a copy of the sample report.</p> <p>This finding was reviewed with the Maintenance Supervisor during the exit conference.</p>		<p>Safety Binder to meet set standards.</p> <p>b The Maintenance Supervisor /designee will ensure an annual fuel quality test for the emergency generator is conducted and documented in the facilities Life Safety Binder to meet set standards.</p> <p>c The Administrator will monitor adherence to the Emergency Preparedness Policy Manual and validate the documentation is in place.</p> <p><b>1 MONITORING</b></p> <p><b>CORRECTIVE ACTION:</b></p> <p>a At least every three years the four-hour load test will be completed to ensure compliance, the Administrator and Maintenance Supervisor/designee will review the Emergency Preparedness Policy Manual and make changes as necessary to meet set standards. Those reviews will be documented as appropriate. The Administrator will present the training results at the Quality Assurance/ Performance Improvement (QA/PI) meeting. Results and system components will be reviewed by the QA/PI Committee with subsequent plans of correction developed and implemented as deemed necessary to ensure compliance is maintained.</p>		

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Bldg. 01	<p>A Life Safety Code Recertification and State Licensure Survey was conducted by the Indiana Department of Health in accordance with 42 CFR 483.90(a).</p> <p>Survey Date: 04/29/24</p> <p>Facility Number: 000174 Provider Number: 155274 AIM Number: 100274810</p> <p>At this Life Safety Code survey, The Waters of Rockport Skilled Nursing Facility was found not in compliance with Requirements for Participation in Medicare/Medicaid, 42 CFR Subpart 483.90(a), Life Safety from Fire and the 2012 edition of the National Fire Protection Association (NFPA) 101, Life Safety Code (LSC), Chapter 19, Existing Health Care Occupancies and 410 IAC 16.2.</p> <p>This one story facility was determined to be of Type V (000) construction and was fully sprinklered. The facility has a fire alarm system with hard wired smoke detectors in the corridors and spaces open to the corridors, plus battery operated smoke alarms in all resident sleeping rooms. The facility has a capacity of 60 and had a census of 31 at the time of this survey.</p> <p>All areas where the residents have customary access were sprinklered and all areas providing facility services were sprinklered, except two detached structures, a wood framed garage used for a maintenance shop and facility storage, as well as a wood framed house used for facility storage.</p> <p>Quality Review completed on 05/02/24</p>			K 0000			

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K 0363 SS=E Bldg. 01	<p>NFPA 101 Corridor - Doors Corridor - Doors Doors protecting corridor openings in other than required enclosures of vertical openings, exits, or hazardous areas resist the passage of smoke and are made of 1 3/4 inch solid-bonded core wood or other material capable of resisting fire for at least 20 minutes. Doors in fully sprinklered smoke compartments are only required to resist the passage of smoke. Corridor doors and doors to rooms containing flammable or combustible materials have positive latching hardware. Roller latches are prohibited by CMS regulation. These requirements do not apply to auxiliary spaces that do not contain flammable or combustible material.</p> <p>Clearance between bottom of door and floor covering is not exceeding 1 inch. Powered doors complying with 7.2.1.9 are permissible if provided with a device capable of keeping the door closed when a force of 5 lbf is applied. There is no impediment to the closing of the doors. Hold open devices that release when the door is pushed or pulled are permitted. Nonrated protective plates of unlimited height are permitted. Dutch doors meeting 19.3.6.3.6 are permitted. Door frames shall be labeled and made of steel or other materials in compliance with 8.3, unless the smoke compartment is sprinklered. Fixed fire window assemblies are allowed per 8.3. In sprinklered compartments there are no restrictions in area or fire resistance of glass or frames in window assemblies.</p> <p>19.3.6.3, 42 CFR Parts 403, 418, 460, 482, 483, and 485</p>						

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	<p>Show in REMARKS details of doors such as fire protection ratings, automatics closing devices, etc.</p> <p>Based on observation and interview, the facility failed to ensure 1 of 2 Med room doors had no impediment to closing and was smoke resistant. This deficient practice could affect over 20 residents, staff, and visitors.</p> <p>Findings include:</p> <p>Based on observations on 04/29/24 between 12:15 p.m. and 2:30 p.m. during a tour of the facility with the Maintenance Supervisor, the east Med Room door behind the Nurse's Station was held wide open with a two gallon container, furthermore, there was a 1/4 inch hole through the middle of the door. Based on interview at the time of observation, the Maintenance Supervisor acknowledged the east Med Room door being held wide open with a two gallon container and the 1/4 inch hole through the door. He further spoke with the Assistant Director of Nursing about the Med room door being held wide open.</p> <p>This finding was reviewed with the Maintenance Supervisor during the exit conference.</p> <p>3.1-19(b)</p>			K 0363	<p><b>K363</b> – It is the intent of the facility to ensure med room doors have no impediment to closing and is smoke resistant to meet set standards.</p> <p><b>1 CORRECTIVE ACTIONS TAKEN:</b></p> <p>a On April 29, 2024, the Maintenance Supervisor/designee removed the two gallon container and repaired the hole in the east med room door to meet set standards. The Administrator verified the repairs on April 30, 2024.</p> <p><b>1 ALL OTHERS WITH POTENTIAL TO BE AFFECTED:</b></p> <p>a All residents and all staff and visitors have the potential to be affected but none were.</p> <p><b>2 MEASURES TO PREVENT REOCCURRENCE:</b></p> <p>a On May 8, 2024, the Administrator in serviced the Maintenance Supervisor/Nursing Staff med rooms doors are not to be propped open and must remain free of holes to meet set standards.</p> <p>b Maintenance Supervisor/DON/designee will inspect all med room doors to ensure they are not propped open and remain free of holes as a part of the facility's Preventive Maintenance Program and document those inspection results</p>		05/27/2024



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K 0918 SS=C Bldg. 01	NFPA 101 Electrical Systems - Essential Electric Syste Electrical Systems - Essential Electric System Maintenance and Testing The generator or other alternate power source and associated equipment is capable of supplying service within 10 seconds. If the 10-second criterion is not met during the monthly test, a process shall be provided to annually confirm this capability for the life		as appropriate. If any issues are discovered, they will be addressed and resolved immediately. The Maintenance Supervisor/designee will review with the Administrator the inspection results. c.The Administrator will monitor adherence to the Preventative Maintenance schedule and validate the Preventative Maintenance documentation is in place. <b>1 MONITORING CORRECTIVE ACTION:</b> a.The inspection results will be presented by the Maintenance Supervisor/designee to the Administrator monthly and the Administrator will present the inspection results at the monthly Quality Assurance/Performance Improvement (QA/PI) meeting. Inspection results and system components will be reviewed by the QA/PI Committee with subsequent plans of correction developed and implemented as deemed necessary to ensure compliance is maintained.		

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	<p>safety and critical branches. Maintenance and testing of the generator and transfer switches are performed in accordance with NFPA 110.</p> <p>Generator sets are inspected weekly, exercised under load 30 minutes 12 times a year in 20-40 day intervals, and exercised once every 36 months for 4 continuous hours. Scheduled test under load conditions include a complete simulated cold start and automatic or manual transfer of all EES loads, and are conducted by competent personnel. Maintenance and testing of stored energy power sources (Type 3 EES) are in accordance with NFPA 111. Main and feeder circuit breakers are inspected annually, and a program for periodically exercising the components is established according to manufacturer requirements. Written records of maintenance and testing are maintained and readily available. EES electrical panels and circuits are marked, readily identifiable, and separate from normal power circuits. Minimizing the possibility of damage of the emergency power source is a design consideration for new installations.</p> <p>6.4.4, 6.5.4, 6.6.4 (NFPA 99), NFPA 110, NFPA 111, 700.10 (NFPA 70)</p> <p>Based on record review and interview, the facility failed to ensure an annual fuel quality test was performed for 1 of 1 diesel powered generator. NFPA 99, Health Care Facilities Code, 2012 Edition Section 6.5.4.1.1.2 states Type 2 EES (Essential Electrical System) generator sets shall be inspected and tested in accordance with Section 6.4.4.1.1.3. Section 6.4.4.1.1.3 states maintenance shall be performed in accordance with NFPA 110, Standard for Emergency and Standby Power Systems, 2010 Edition, Chapter 8. NFPA 110, Section 8.3.8 states a fuel quality test shall be</p>			K 0918	<p><b>K918</b> – It is the intent of the facility to ensure an annual fuel quality test is performed for diesel powered generator to meet set standards.</p> <p><b>1 CORRECTIVE ACTIONS TAKEN:</b></p> <p>a On May 10, 2024, the Maintenance Supervisor obtained a copy of the annual fuel quality test for the diesel generator from the 2/21/24 semiannual</p>		05/27/2024

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	<p>performed at least annually using tests approved by ASTM standards. This deficient practice could affect all residents, as well as staff and visitors.</p> <p>Findings include:</p> <p>Based on record review on 04/29/24 between 9:30 a.m. and 12:15 p.m. with the Maintenance Supervisor present, there was documentation of an annual generator inspection/service dated 08/22/23, and a semi-annual generator inspection/service dated 02/21/24, however, there was no documentation of an annual fuel quality test for the diesel generator available for review during the past 12 month period. Based on interview at the time of record review, the Maintenance Supervisor said a diesel fuel sample was taken during the 02/21/24 semi-annual inspection/service of the generator by the facility's vendor, however, the facility has not been sent a copy of the sample report.</p> <p>This finding was reviewed with the Maintenance Supervisor during the exit conference.</p> <p>3.1-19(b)</p>				<p>inspection/service and documented the results in the facilities Life Safety Binder to meet set standards. The Administrator verified the work on May 10, 2024.</p> <p><b>2 ALL OTHERS WITH POTENTIAL TO BE AFFECTED:</b></p> <p>a All residents and all staff and visitors have the potential to be affected but none were.</p> <p><b>3 MEASURES TO PREVENT REOCCURRENCE:</b></p> <p>a The Administrator inserviced the Maintenance Supervisor/designee on the requirement that an annual fuel quality test for the emergency generator must be conducted and documented in the facilities Life Safety Binder to meet set standards.</p> <p>b The Maintenance Supervisor/designee will ensure an annual fuel quality test for the emergency generator is conducted and documented in the facilities Life Safety Binder as a part of the facility's Preventive Maintenance Program and document those inspection results as appropriate. If any issues are discovered, they will be addressed and resolved immediately. The Maintenance Supervisor/designee will review with the Administrator the inspection results.</p> <p>c The Administrator will monitor adherence to the Preventative Maintenance</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  155274	X2) MULTIPLE CONSTRUCTION A. BUILDING 01 B. WING		X3) DATE SURVEY COMPLETED 04/29/2024
NAME OF PROVIDER OR SUPPLIER  WATERS OF ROCKPORT SKILLED NURSING FACILITY, THE			STREET ADDRESS, CITY, STATE, ZIP COD 815 W WASHINGTON ST ROCKPORT, IN 47635		
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K 0920 SS=E Bldg. 01	NFPA 101 Electrical Equipment - Power Cords and Extens Electrical Equipment - Power Cords and Extension Cords Power strips in a patient care vicinity are only used for components of movable patient-care-related electrical equipment (PCREE) assemblies that have been assembled by qualified personnel and meet the conditions of 10.2.3.6. Power strips in the patient care vicinity may not be used for non-PCREE (e.g., personal electronics), except in long-term care resident rooms that do not use PCREE. Power strips for PCREE meet UL 1363A or UL 60601-1. Power strips for non-PCREE in the patient care rooms (outside of vicinity) meet UL 1363. In non-patient care rooms, power strips meet		schedule and validate the Preventative Maintenance documentation is in place. <b>4 MONITORING CORRECTIVE ACTION:</b> a The inspection results will be presented by the Maintenance Supervisor/designee to the Administrator monthly and the Administrator will present the inspection results at the monthly Quality Assurance/Performance Improvement (QA/PI) meeting. Inspection results and system components will be reviewed by the QA/PI Committee with subsequent plans of correction developed and implemented as deemed necessary to ensure compliance is maintained.		

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	<p>other UL standards. All power strips are used with general precautions. Extension cords are not used as a substitute for fixed wiring of a structure. Extension cords used temporarily are removed immediately upon completion of the purpose for which it was installed and meets the conditions of 10.2.4. 10.2.3.6 (NFPA 99), 10.2.4 (NFPA 99), 400-8 (NFPA 70), 590.3(D) (NFPA 70), TIA 12-5 Based on observation and interview, the facility failed to ensure power strips and multi-plug adapters were not used as a substitute for fixed wiring in 2 of 8 smoke compartments. LSC 19.5.1 requires utilities to comply with Section 9.1. LSC 9.1.2 requires electrical wiring and equipment to comply with NFPA 70, National Electrical Code, 2011 Edition. NFPA 70, Article 400.8 requires that, unless specifically permitted, flexible cords and cables shall not be used as a substitute for fixed wiring of a structure. This deficient practice could affect mostly staff.</p> <p>Findings include:</p> <p>Based on observations on 04/29/24 between 12:15 p.m. and 2:30 p.m. during a tour of the facility with the Maintenance Supervisor, the following was noted:</p> <p>a. There was refrigerator, microwave oven, and coffee maker plugged into a power strip in the MDS Office.</p> <p>b. There was a refrigerator plugged into a multi-plug adapter in the east Med Room. Based on interview at the time of each observation, the Maintenance Supervisor acknowledged the use of the power strip and multi-plug adapter and said he was not aware they were being used. The Maintenance Supervisor removed the power strip and multi-plug adapter at the time of each observation.</p>			K 0920	<p><b>K920</b> – It is the intent of the facility to ensure power strips and multi plug adapters are not used as a substitute for fixed wiring in smoke compartments to meet set standards.</p> <p><b>1.CORRECTIVE ACTIONS TAKEN:</b></p> <p>1.On April 29, 2024, the Maintenance Supervisor/designee removed the power strip in the MDS office to meet set standards. The Administrator verified the removal on April 30, 2024.</p> <p>2.On April 29, 2024, the Maintenance Supervisor/DON/designee removed the multi plug adapter in the east Med Room to meet set standards. The Administrator verified the removal on April 30, 2024.</p> <p><b>2.ALL OTHERS WITH POTENTIAL TO BE AFFECTED:</b></p> <p>1.All residents and all staff and visitors have the potential to be affected but none were. On April 30, 2024, the Maintenance Supervisor/designee inspected all rooms throughout the facility for</p>		05/27/2024

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	<p>This finding was reviewed with the Maintenance Supervisor during the exit conference.</p> <p>3.1-19(b)</p>		<p>power strips and multi plug adapters and found no other negative findings.</p> <p><b>3.MEASURES TO PREVENT REOCCURRENCE:</b></p> <p>1.On May 8, 2024, the Administrator inserviced the Maintenance Supervisor/designee/all other staff that multi plug adapters and power strips are not to be used as a substitute for fixed wiring to meet set standards.</p> <p>2.Maintenance Supervisor/designee will inspect all rooms throughout the facility monthly to ensure they do not have multi plug adapters or power strips in use as a part of the facility's Preventive Maintenance Program and document those inspection results as appropriate. If any issues are discovered, they will be addressed and resolved immediately. The Maintenance Supervisor/designee will review with the Administrator the inspection results.</p> <p>3.The Administrator will monitor adherence to the Preventative Maintenance schedule and validate the Preventative Maintenance documentation is in place.</p> <p><b>4.MONITORING CORRECTIVE ACTION:</b></p> <p>1.The inspection results will be presented by the Maintenance Supervisor/designee to the Administrator monthly and the</p>		

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					Administrator will present the inspection results at the monthly Quality Assurance/Performance Improvement (QA/PI) meeting. Inspection results and system components will be reviewed by the QA/PI Committee with subsequent plans of correction developed and implemented as deemed necessary to ensure compliance is maintained.		