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	880074	A. BUILDING: _____ B. WING _____	10/13/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOUSTON WOMENS REPRODUCTIVE SERVICES	5225 KATY FREEWAY, SUITE 370 HOUSTON, TX 77007

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6 000	TAC 139.1 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (b) Scope and applicability. (1) Licensing requirements. (A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements. (B) The following need not be licensed under this chapter: (i) a hospital licensed under Health and Safety Code, Chapter 241; (ii) an ambulatory surgical center licensed	6 000		

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6 000	Continued From page 1 under Health and Safety Code, Chapter 243; or (iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period. (2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed). Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (b) Scope and applicability. (1) Licensing requirements.	6 000		

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6 000	Continued From page 2 (A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements. (B) The following need not be licensed under this chapter: (i) a hospital licensed under Health and Safety Code, Chapter 241; (ii) an ambulatory surgical center licensed under Health and Safety Code, Chapter 243; or (iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period. (2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed).	6 000		

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Health and Human Services Commission

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6 033	Continued From page 6	6 033		
6 033	TAC 139.48 Physical and Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; (B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area; (C) have a separate recovery room if moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia are administered at the facility; (D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph; (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings.	6 033		

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6 033	Continued From page 7 If other food is provided by the facility, it shall be subject to the requirements of Chapter 228 of this title (relating to Retail Food); (G) provide clean hand washing facilities for patients and staff including running water, and soap; (H) have two functioning sinks and a functioning toilet; and (I) have equipment available to sterilize instruments, equipment, and supplies in accordance with §139.49(d) of this title (relating to Infection Control Standards) before use in the facility. (2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action in facilities that provide vacuum aspiration. (3) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction shall minimize disruptions of existing functions. Access, exit ways, and fire protection shall be maintained so that the safety of the occupants shall not be jeopardized during construction. This Requirement is not met as evidenced by: Based on observation and interview the facility failed to ensure a safe environment in that medical equipment testing for electrical safety was not completed on all necessary equipment in the facility. Findings:	6 033		

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6 033	Continued From page 8 The facility Administrator failed to ensure all electrical medical equipment had electrical safety testing completed. Documents Reviewed: On 10/13/2020 the current Houston Women's Reproductive Services job description for the Administrator: Responsibilities: Overall coordination of clinic functions. Staff Responsibilities ... 7. Provide a safe environment for staff to work and patients to receive quality care. Observation: Observation on 10/12/2020 at 10:00 a.m. along with Facility Administrator, Employee ID # 51 of the abortion facility the following equipment was observed with no electrical safety checks: 1. Patient exam room #3 - Portable Oral suction machine - Yuwell 7EC portable phlegm suction unit 2. Patient exam room #3 - Free standing floor exam lamp 3. Laboratory area: 1 -Rapid Hemoque Hb201 4. Laboratory area: 1 Rh View boxRVB-8L Interview: Employee ID #51 also confirmed there had not been electrical safety testing performed on the Oral suction machine, free standing floor exam lamp, Rapid Hemoque Hb201 and Rh Vew boxRVB-8L.	6 033	Facility failed to have annual electrical safety inspection on 4 pieces of new equipment. Administrator will develop a list of all medical equipment and ensure items have electrical safety inspections. This list will be updated when there is a change in equipment. QA committee will reviewed in quarterly meetings.	11/01/2020
6 034	TAC 139.49 Infection Control Standards	6 034		

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6 034	Continued From page 9 (a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the transmission of post-procedure infections. These policies shall include, but not be limited to, the prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Mycobacterium tuberculosis (TB), and Streptococcus species (S. spp.); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies. (b) Prevention and control of the transmission of HIV, HBV, HCV, TB, and S. spp. (1) Universal/standard precautions. (A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph. (i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments. (ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and apply them to all patients receiving care in facilities, regardless of their diagnosis or presumed infection status. (I) Universal/standard precautions apply to:	6 034		

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6 034	Continued From page 10 (-a-) blood; (-b-) body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood; (-c-) nonintact skin; and (-d-) mucous membranes. (II) Universal/standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in facilities. (B) A licensed abortion facility shall establish procedures for monitoring compliance with universal/standard precautions described in subparagraph (A) of this paragraph. (2) Health care workers infected with the HIV or HBV. A licensed abortion facility shall adopt, implement, and enforce a written policy to ensure compliance of the facility and all of the health care workers within the facility with the Health and Safety Code, Chapter 85, Subchapter I, concerning the prevention of the transmission of HIV and HBV by infected health care workers. (3) Educational course work and training. A licensed abortion facility shall require its health care workers to complete educational course work or training in infection control and barrier precautions, including basic concepts of disease transmission, scientifically accepted principles and practices for infection control and engineering and work practice controls. To fulfill the requirements of this paragraph, course work and training may include formal education	6 034		

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6 034	Continued From page 11	6 034		

courses or in-house training or workshops provided by the facility. The course work and training shall include, but not be limited to:

(A) HIV infection prevention; and

(B) HBV, HCV, TB, and S. spp. infection prevention based on universal/standard precautions as defined in paragraph (1) of this subsection;

(C) bidirectional aspect of disease transmission; and

(D) epidemic control.

(c) Cleaning and laundry policies and procedures.

(1) A licensed abortion facility shall develop, implement, and enforce written policies and procedures on cleaning the procedure room(s).

(2) A licensed abortion facility shall develop, implement, and enforce written policies and procedures for the handling, processing, storing, and transporting of clean and dirty laundry.

(3) A licensed abortion facility may provide cleaning and laundry services directly or by contract in accordance with Occupational Safety and Health Administration's Standards, 29 Code of Federal Regulations, Subpart Z. Bloodborne Pathogens.

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities

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performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(1) Supervision. The decontamination, disinfection, and sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training, or experience.

(2) Quantity of sterile surgical instruments. The facility shall ensure that surgical instruments are sufficient in number to permit sterilization of the instrument(s) used for each procedure and adequate to perform conventional cervical dilatation and curettage if this procedure is available at the facility.

(3) Inspection of surgical instruments.

(A) All instruments shall undergo inspection before being packaged for reuse or storage. Routine inspection of instruments shall be made to assure clean locks, crevices, and serrations.

(B) Inspection procedures shall be thorough and include visual and manual inspection for condition and function.

(i) Cutting edges shall be checked for sharpness; tips shall be properly aligned, and box locks shall be clean and free from buildup of soap, detergent, dried blood, or tissue.

(ii) There shall be no evident cracks or

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6 034	Continued From page 13 fissures in the box locks, and the hinges shall work freely. (iii) Ratchets shall hold and be routinely tested. (iv) There shall be no corrosion or pitting of the finish. (C) Instruments needing maintenance shall be taken out of service and repaired by someone qualified to repair surgical instruments. (D) To protect the instrument and its protective finish, impact markers or electric engravers shall not be used for instrument identification. Instrument identification shall be accomplished by the instrument manufacturer, employing methods which shall not damage the instrument or its protective finish. (4) Items to be disinfected and sterilized. (A) Critical items. (i) Critical items include all surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body and shall be sterilized in accordance with this subsection. (ii) All items that come in contact with the sterile field during the operative procedure shall be sterile. (B) Semicritical items. (i) Semicritical items include items that come in contact with nonintact skin or mucous	6 034		

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membranes. Semicritical items shall be free of microorganisms, except bacterial spores. Semicritical items may include respiratory therapy equipment, anesthesia equipment, bronchoscopes, and thermometers.

(ii) High-level disinfection shall be used for semicritical items.

(C) Noncritical items.

(i) Noncritical items include items that come in contact with intact skin.

(ii) Intermediate-level or low-level disinfection shall be used for noncritical items.

(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.

(A) Equipment. A licensed abortion facility shall provide sterilization equipment adequate to meet the requirements of this paragraph for sterilization of critical items. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of critical items.

(B) Environmental requirements. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the written policies and procedures for their use shall be such as to effectively separate soiled or

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contaminated supplies and equipment from the clean or sterilized supplies and equipment.

(i) A facility shall have a sink for hand washing. This sink shall not be used for cleaning instruments or disposal of liquid waste.

(ii) A facility shall have a separate sink for cleaning instruments and disposal of liquid waste. Hand washing shall only be performed at this sink after it has been disinfected.

(C) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment. Cleaning is the removal of all adherent visible soil from the surfaces, crevices, joints, and lumens of instruments. Decontamination is the physical/chemical process that renders an inanimate object safe for further handling.

(ii) One of the following methods of cleaning and decontamination shall be used as appropriate.

(I) Manual cleaning. Manual cleaning of instruments at the sink is permitted.

(II) Ultrasonic cleaning. Ultrasonic cleaning of instruments cleans by cavitation and reduces the need for hand scrubbing. When grossly soiled items are placed in the ultrasonic cleaner the water shall be changed more than once a shift. If using this method for cleaning, chambers shall be covered to prevent potential hazards to personnel from aerosolization of the contents.

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6 034	Continued From page 16 (III) Washer-sterilizers. Washer-sterilizers clean by using rotating spray arms to create water jets that clean by impingement and appropriate soap and disinfectant. These machines shall reach a temperature of 140 degrees Celsius (285 degrees Fahrenheit). (IV) Washer-decontaminator machines. Washer-decontaminator machines clean by numerous water jets and a high pH of detergent even if instruments are grossly soiled. The thorough cleaning is followed by a neutralizing rinse to quickly restore the pH to neutral. (iii) All articles to be sterilized shall be arranged so all surfaces shall be directly exposed to the sterilizing agent for the prescribed time and temperature. (D) Packaging. (i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds. (ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave. (E) External chemical indicators.	6 034		

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6 034	Continued From page 17 (i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process. (ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications. (F) Biological indicators. (i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (e.g., Bacillus stearothermophilus for steam sterilizers). (ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers. (iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load. (iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations. (v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator. (G) Sterilizers.	6 034		

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6 034	Continued From page 18 (i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions. (ii) Other sterilizers shall be used in accordance with the manufacturer's instructions. (H) Maintenance of sterility. (i) Items that are properly packaged and sterilized shall remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised. (ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations. (iii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing. (I) Commercially packaged items. Commercially packaged items are considered sterile according to the manufacturer's instructions. (J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.	6 034		

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6 034	Continued From page 19 (i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage. (ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity. (iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised. (iv) Storage of supplies shall be in areas that are designated for storage. (K) Disinfection. (i) The manufacturer's written instructions for the use of disinfectants shall be followed. (ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use. (iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas. (L) Performance records. (i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of two years. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at	6 034		

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6 034	Continued From page 20 desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) identification of operator(s); (VI) results of biological tests and dates performed; and (VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts). (M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review to the facility within two hours of request by the department. This Requirement is not met as evidenced by: Based on observation, record review and interview the facility failed to implement their infection control policies and procedures to minimize the transmission of infections.	6 034		

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6 034	Continued From page 21 Findings: 1. The facility failed to ensure manufactures guidelines and universal/standard precautions were followed for the use of disinfection of reusable medical devices and disinfection of contaminated surfaces. 2. The facility failed to ensure that expired vials of multidose medication were properly labeled and disposed of after expiration date. 3. The facility failed to ensure the contents of the medication refrigerator did not contain blood specimens. Policy Reviewed: Facility of the facility's current policy on 10/12/2020 - Review of Revital-Ox Resert HLD solution per Ultrasound manufactures recommendations: Technical Data Monograph, Revital-Ox Resert High Level Disinfection Performance Benefits: The Revital-Ox RESERT HLD solution has been formulated to be a safe and easy-to-use liquid high-level disinfectant that is environmentally friendly. It has an 18-month shelf life and needs no special venting during use or storage. Revital-Ox RESERT HLD solution may be disposed directly into sanitary sewers. Use Conditions: After opening, the solution may be stored for use up to 90 days (provided the 90 days does not extend past the expiration date on the container). When poured into a secondary container (i.e. basin), Revital-Ox RESERT HLD solution can be	6 034	Administrator will be responsible for ensuring manufactures guidelines and universal/standard precautions are followed when disinfecting medical equipment and contaminated surfaces. Medically approved solutions/wipes will be used in patient areas where possible contamination may occur. All staff will review these guidelines to ensure facility compliance. LVN shall be respons ble for verifying expiration date of high level disinfectant solution each day of use when performing daily test strip. Expired solutions will be discarded immediately.	11/01/2020

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6 034	Continued From page 22 re-used for up to 21 days, or until its concentration falls below the minimum recommended concentration (MRC) of 1.5% hydrogen peroxide. The MRC must be monitored before each use using the Revital-Ox (Trademark) RESERT® R60 Solution Test Strip. Manufactory Guidelines - Review of Steris Revital-Ox Resert High Level Disinfectant for medical devices and instruments: manufactory's guidelines. Indications for Use: High level disinfectant is a reusable high level disinfectant solution for processing heat sensitive medical devices and instruments, for which heat sterilization is suitable, when used according to the Directions for Use. Reuse Period for High Level Disinfection: Solution may be reused up to a maximum of 21 days, provided the required conditions of hydrogen peroxide concentration, temperature exist based upon monitoring described in the Directions for Use. Do not rely solely on the days in use. The hydrogen peroxide concentration of Revital-Ox-Resert High Level Disinfectant solution during its use-life must be verified before each use with the Revital-Ox Resert R60 Test Strip, which will indicate that the Minimum Recommended Concentration of 1.5% hydrogen peroxide has been met. Rinsing Instructions: 5. Following removal from Revital-Ox Resert high Level Disinfectant solution, thoroughly rinse the medical devise by immersing it completely in water. Use sterile water or potable water as required by facility policies .... 6. Keep the instrument or medical device immersed for a minimum of 1 minute in durations, unless longer is specified by the	6 034		

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6 034	Continued From page 23	6 034		

instrument manufacturer 8. Remove device and discard rinse water. Do not reuse the water for rinsing or any other purpose.

Potable Water Rinse: For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable. When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the medical device with microorganisms which may be present in potable water supplies.

Review of Basic User Manual for Ultrasound Machine Section 10.1.4

1. There is a cleared list of sterilant and high-level disinfectants for use in processing reusable medical and dental devices on the FDA website.

2. Use the liquid disinfectant that meets local laws and regulations or the recommended disinfectant/sterilant.

3. The probe sheath may be damaged during exam and contamination risk level caused by the damaged sheath is difficu.t to estimate. Therefore, probe sheath cannot change the level of disinfection for a probe. Please clean and sterilize (or high level disinfect) the endocavitary probe and clean and sterilize the probe for biopsy and coming into contact blood after exam.

4. Do not use an expired disinfectant/sterilant. Store the probe in a sterile environment and review its expiration date before use. Disinfection Levels Vaginal Probe - Semi-critical - A device that comes into contact with intact mucous membranes and does not ordinary penetrate sterile tissue. Level of disinfection -

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6 034	Continued From page 24 Hight-level disinfection, Application - Endocavitary probe. To disinfect the endocavitary probe: You should disinfect the endocavitary probe before and after each use. Perform the following steps: 1. Clean the probe 2. Perform the high-level disinfection to the probe 3. Rinse the probe with running sterile water to completely removed the residual disinfectant 4. Dry the probe with a lint-free soft dry cloth Review of Center for Disease Control (CDC) Guidelines for infection control guidelines for disinfection; Review on 10/13/2020 of the CDC website https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). Alcohol: Overview "In the healthcare setting, "alcohol" refers to two water-soluble chemical compounds-ethyl alcohol and isopropyl alcohol-that have generally underrated germicidal characteristics 482. FDA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores." Observation: Observation on 10/12/2020 at 10:00 a.m. along	6 034		

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6 034	Continued From page 25 with Facility Administrator, Employee ID # 51 of the abortion facility the following equipment was observed with no electrical safety checks: 1. Patient exam room #3 - Portable Oral suction machine - Yuwell 7EC portable phlegm suction unit 2. Patient exam room # 3 - Free standing floor exam lamp 3. Laboratory area: 1 -Rapid Hemoque Hb201 4. Laboratory area: 1 Rh View boxRVB-8L Observation of the dirty utility room on 10/12/2020 at 10:15 a.m. along with the Employee ID #51 and Licensed Vocational Nurse Employee ID #52 a blue container containing a clear liquid was observed. The container was identified by Employee ID #52 as Revita-Ox Resert High Level Disinfectant Solution used to disinfect a reusable a vaginal ultrasound probe. Further observation noted the contain was labeled 9-15-20 and 10-6-20 (expired). No sterile water was observed in the utility room. Also observed was a container Labeled Revital-Ox, Resert R60 Solution Text Strip. For monitoring of Revital-Ox Resert High Level Disinfectant-Chemosterilant and Resert XL HLD High Level Disinfectant, Expiration date 2021-01-01. Observation on 10/12/2020 10:45 a.m. along with Facility Administrator, Employee #51 of the medication refrigerator in the laboratory area 1 vial of multidose (10 test vial), 1 ml, Tuberculin, Purified Protein Derivative was observed. Vial was labeled with an open date of 7/20 and expiration date 2/21. Observation on the morning of 10/12/2020 of the patient treatment areas and the laboratory area	6 034		

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6 034	Continued From page 26 no high level medically approved disinfection solution or wipes were found in the treatment areas for disinfection of treatment rooms after use or for disinfection of reusable medical equipment after use. Wipes of 75% Alcohol packets were identified in multiple areas of the facility. Alcohol wipes were labeled to me Caresour, Distributed by: OneCare Products 75% Alcohol Wipes. Package list: Active Ingredient: Alcohol 75%; Uses; for hand sanitizing to decrease bacteria on the skin, apply topically to skin to help prevent cross contamination, not recommended for repeated use, dries in seconds, Wipes were not identified to be approved for disinfection of medical equipment or as a surface disinfection approved by FDA. Interviews: Interview on 10/12/2020 at 3:00 p.m. with the Facility Administrator, Employee ID #51 confirmed the multidose vial of Tuberculin, Purified Protein Derivative, D was not labeled as required and needed to have the complete date including the month, date and year on the container. Dates marked on the container only included month and year of the opening date and expiration date. Employee ID #51 confirmed the medication was a multidose vial and should have been thrown out 28 days after opening. Interview with employee ID #51 concerning disinfecting reusable equipment (ultrasound machine) and disinfection of patient treatment rooms verified the facility used Alcohol wipes. Employee ID #51 presented a package of 75% Alcohol wipes that were used to wipe down equipment, disinfect patient treatment areas and the laboratory area after use. Employee ID #51 confirmed she was not aware the use of Alcohol	6 034		

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6 034	Continued From page 27 wipes were not appropriate for disinfection of reusable medical equipment and surface disinfection of treatment areas. Interview on 10/12/2020 at 3:30 p.m. with Licensed Vocational Employee ID #52 confirmed the disinfection solution used to disinfect the reusable vaginal ultrasound probes had expired on 10/6/2020 and should have been discarded. Employee ID #52 stated the solution was only good for 21 days. Employee ID #52 ask if she had completed the daily testing of the disinfection solution with the biological indicators, Employee ID #52 stated yes, the solution was tested earlier this morning and the results were the disinfection solution passed and documented on the disinfection log. Employee ID #52 confirmed there was no sterile water to rinse the vaginal probe after removing it from the disinfection solution and stated she used tap water. Employee ID #52 stated that she was not aware the probe had to be rinsed with sterile water. Interview with Employee ID #51 on 10/12/2020 at 3:30 p.m. was asked how the staff was trained on disinfection of the ultrasound probe. Employee ID #51 stated they just followed the manufactory's recommendations. Employee ID #51 confirmed that no onsite training was provided by the manufactory. Employee ID #51 stated that she was unaware of the manufactory's guidelines to rinse the probe after it is removed from the high-level disinfectant with sterile water. Interview on 10/13/2020 at 2:00 p.m. with Facility Administrator Employee ID #51 confirmed they follow CDC (Center for Disease Control) guidelines and are members of the National Abortion Federation and use their guidelines which also follow the CDC guidelines.	6 034		

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