Hello!

Enclosed is our plan of correction. This is all very new to me so please let me know if something isn't correct or if you need more information. I can be reached Monday - Friday from 9am - 4:30pm at 540-981-1246.

Thank you for your patience and guidance during this process.

Sincerely,
Jennifer Gusitt

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-0014	A. BUILDING _____ B. WING _____	07/18/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ROANOKE MEDICAL CENTER FOR WOMEN	1119 2ND STREET SW ROANOKE, VA 24016

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T 000	12 VAC 5- 412 Initial comments An announced Initial Licensure Abortion Facility inspection and two complaint investigations were conducted at the above referenced facility on July 17 through 18, 2012 2 by two (2) Medical Facilities Inspectors from the Virginia Department of Health's, Office of Licensure and Certification. Ten personnel files and one clinical record were reviewed.. A tour of the facility was conducted with staff interviews. The facility was out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified, cited, and will follow in this report.	T 000		
T 035	12 VAC 5-412-150 Policy and procedure manual. Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics: 1. Personnel; 2. Types of elective and emergency procedures that may be performed in the facility; 3. Types of anesthesia that may be used; 4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge; 5. Obtaining written informed consent of the patient prior to the initiation of any procedures; 6. When to use ultrasound to determine gestational age and when indicated to assess patient risk; 7. Infection prevention; 8. Risk and quality management; 9. Management and effective response to	T 035		

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

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T 035	Continued From Page 1 medical and/or surgical emergency; 10. Management and effective response to fire; 11. Ensuring compliance with all applicable federal, state and local laws; 12. Facility security; 13. Disaster preparedness; 14. Patient rights; 15. Functional safety and facility maintenance; and 16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines. This RULE: is not met as evidenced by: Based on review of the facility's Policy and	T 035		

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T 035	Continued From Page 2 Procedure Manual and interview with Staff #4, it was determined that no documentation of an annual review was available for the Surveyor to review as required in Section 12 VAC 5-412-150. The findings included: 1. The Surveyor reviewed the Policy and Procedure Manual on July 17, 2012 at various times in the agency's office. No signatures were available by the Governing Body stating that the Policy and Procedure Manual had been reviewed. 2. Staff #4 acknowledged during interview that the Governing Body had not reviewed the Policy and Procedure Manual. This interview occurred in the agency's office on July 18, 2012, at 2;15 p.m.	T 035	T035 ① Policy + procedure manuals had not been updated annually. This was immediately corrected by reviewing policy + procedure manual and documenting it had been done ② Administrator will review manual w/ governing bodies annually to ensure this does not happen again ③ a document was created for governing body to sign off as manual is reviewed ④ Administrator + governing body will review annually or as needed ⑤ In compliance as of 7/19/12	
T 070	12 VAC 5-412-170 C Personnel C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility. This RULE: is not met as evidenced by: Based on review of personnel files and interview with Staff #1, it was determined that three (#3,#4 and #10) of five (#1,#3-#4 and #9-#10) staff members who have access to narcotics failed to have criminal record check reports available for review as required in Section 12 VAC 5-412-170. The findings included: 1. The Surveyor reviewed personnel files on July 17, 2012 , at 10:20 a.m., in the agency's office. Three (#3,#4 and #10) staff members who had	T 070	T070 ① Three staff members who have access to narcotics did not have completed criminal background checks. Paperwork had been filed but not returned yet. This was corrected immediately when the criminal records on all three employees was received in the mail and put in employee records ② All criminal background checks will be conducted immediately upon hire for anyone to access to narcotics. ③ Procedure will be to conduct criminal checks prior to new employee start date for those who will have access to narcotics.	

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T 070	Continued From Page 3 access to narcotics failed to have results of criminal records checks in the personnel file for the Surveyor to review. 2. Staff Member #1 acknowledged that the results of the criminal records checks were not available for the Surveyor to review. This interview occurred in the agency's office on July 17, 2012, at 10:40 a.m.	T 070	(4) Medical Director will monitor this and conduct criminal checks upon hire by submitting background check requests immediately and place in employee files. (5) This deficiency has been corrected as of 8/9/12.	8/9/12
T 095	12 VAC 5-412-170 H Personnel H. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. This RULE: is not met as evidenced by: Based on employee record review and staff interview, the center staff failed to ensure job descriptions for employees were reviewed at least annually for eight (#2-#8 and #10) of ten (#1-#10) employee records reviewed and no policy and procedure for reporting licensed and certified staff to the Board of Health Professions as required in Section 12 VAC 5-412-170. H.3 and 5.	T 095	(1) Staff evaluations had not been completed annually. This was corrected immediately by completing all staff evaluations and reviewing them with staff members. (2) To ensure this is not a problem in the future, staff evals will be done the first week in August each year. (3) The policy will be that all staff are evaluated annually. Self evaluations conducted & then reviewed w/ administrati (4) Administrator/medical director will carry out these evaluations each year during the first week of August (5) As of August 22, all staff evals have been conducted and will be maintained annually.	8/22/12

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T 095	Continued From Page 4 The findings included: 1. On July 17, 2012, at 10:00 a.m., employee records were reviewed in the facility's office. Of the ten records reviewed, eight employees did not have evidence that the job descriptions were reviewed at least annually in their personnel record. The employees were as follows: Employee #2 - date of hire (DOH) August 22, 1988, #3 - DOH August, 14, 1980, #4 - DOH 9/2010, #4 - DOH September 31, 2008, #5 - DOH April 21, 1998, #6 - DOH December 15, 2000, #7 - DOH January 7, 1981, #8 - DOH January 20,2005, 08, #10 - DOH April 21, 1998. Review of the Policy and Procedure manual had no process for reporting to the Deportment of Health Professions any violations by licensed and certified employees. 2. On July 17, 2012, at 10 :30 a.m., Staff #1 acknowledged during interview, that the annual evaluations were not completed on all staff. Staff #1 acknowledged there was no policy to report staff to the Board of Nursing. This interview occurred in the facility's office.	T 095	T095 cont ① There was no policy for reporting staff violations to the Department of Health. This was corrected immediately by obtaining a copy of this policy from our main clinic ② Now that the procedure/policy is in our manual, its absence will not happen again. ③ The policy/procedure violations will be reported to the appropriate board w/in the Department of Health immediately ④ The clinic administrator will be responsible for monitoring staff and reporting any violations immediately ⑤ The policy was added into our manual on 8/1/12	8/1/12
T 165	12 VAC 5-412-220 A Infection prevention A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.	T 165		

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T 165	Continued From Page 5 1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review. This RULE: is not met as evidenced by: Based on observation, interview and record review the facility failed to review and have a process for documenting the annual review of their infection control policies and procedures. The findings include: Observation and review of the facility's infection prevention plan, policies and procedures did not provide evidence of at least annual review. The facility's infection prevention plan, policies and procedures did not include a process for incorporation of recommendations, changes and updates. The facility's current infection prevention plan, policies, and procedures did not have written documentation of review by the administrator or appropriate members of the clinical staff. During an interview conducted on July 17, 2012 at 3:59 p.m., Staff #1 acknowledged the facility did not have written documentation that the administrator or appropriate clinical staff had reviewed their infection prevention plan, policies and procedures. Staff #1 reported the facility did not have a process for at least annual review of	T 165 T165	① There was no documentation of clinical staff having reviewed infection control plan nor was there a method of documenting if + when changes had been made to these plans/ procedures. This was corrected immediately by creating a form to document the date and type of changes made to infection prevention policies. ② Now that these documents are in place, they will be utilized + maintained to prevent this from happening again. ③ The process is that infection control plan will be reviewed annually by all clinical staff. They will sign + date review form indicating their competency. Any updates made will be documented + signed off on by appropriate administrative staff. ④ Governing body will review + update any changes to infection control plan by meeting annually to review and discuss. Administration will ensure all staff review	

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T 165	Continued From Page 6 their infection prevention plan, policies and procedures to update and incorporate recommendations and changes. Staff #1 stated the policies were reviewed at the parent office. An interview was conducted on July 18, 2012 at 2:28 p.m. with Staff #1. Staff #1 reported there was no additional information to present related to written documentation of review or a process for annual review of their infection prevention plan, policies and procedures.	T 165	infection prevention plan at the same time as annual employee evals and at the time of hire for new employees. ⑤ - in place as of 8/9/12.	
T 170	12 VAC 5-412-220 B Infection prevention B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration. 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.	T 170		

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T 170	Continued From Page 7 This RULE: is not met as evidenced by: Based on record review and interview the facility failed to include policies and procedures, which demonstrated compliance with requirements specified by the U.S. Occupational Safety & Health Administration (OSHA) related to blood-borne pathogen exposure. The findings included: Review of the facility's infection prevention plan, policies and procedures conducted on July 17, 2012 did not reveal inclusion of OSHA's requirement related to prevention and risk associated with blood-borne pathogen exposure. An interview was conducted on July 17, 2012 at 3:59 p.m., with Staff #1. Staff #1 reviewed the facility's infection control policies and procedures. Staff #1 reported the policies did not include OSHA requirements related to blood-borne pathogen exposure and staff safety. In part "OSHA's Bloodborne Pathogens Standard requires employers to provide information and training to workers. Employers must ensure that their workers receive regular training that covers all elements of the standard including, but not limited to: information on bloodborne pathogens and diseases, methods used to control occupational exposure, hepatitis B vaccine, and medical evaluation and post-exposure follow-up procedures. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker ' s occupational exposure. (29 CFR 1910.1030 </pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051>)"	T 170	T170 ① No inclusion of OSHA requirements regarding blood-borne pathogen exposure. This was corrected immediately by including OSHA's reporting standards in the infection control portion of the policy & procedure manual. ② Now that these standards are included in the manual we should not be deficient again. ③ The procedure is that we follow the appropriate steps outlined in the "how to report to OSHA" guidelines which are in the policy & procedure manual. Employees are provided with this information upon hire and annually when we review the manual. ④ Administration ensured this information was included in the policy and procedure manual and will ensure all staff are familiar w/ the procedure when they review the policy manual annually. ⑤ This is currently in place	7/19/12

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T 175	Continued From Page 8	T 175		
T 175	12 VAC 5-412-220 C Infection prevention C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines; 8. Procedures for appropriate disposal of non-reusable equipment; 9. Policies and procedures for maintenance/repair of equipment in accordance	T 175		

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T 175	Continued From Page 9 with manufacturer recommendations; 10. Procedures for cleaning of environmental surfaces with appropriate cleaning products; 11. An effective pest control program, managed in accordance with local health and environmental regulations; and 12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department. This RULE: is not met as evidenced by: Based on observations, interviews and record review the facility failed to develop and implement polices/procedures for the prevention and control of infections as evidenced by: 1. Failing to provide adequate hand washing equipment in the "Dirty" utility room. 2. Multiple use of a single-use product and failing to disinfect the single-use vacutainer needle holders between patient lab draws. Staff used of a sponge to clean the procedure jars and failed to disinfect procedure jars and stoppers between patients. 3. Failure to disinfect three (3) of three recovery room cots between patients and one (1) of one lab chair. 4. The policy for linens did not include the facilities current practice. The findings include: 1. An observation conducted on July 17, 2012 at 9:38 a.m., with Staff #1 during the initial tour of the facility revealed the "Dirty" utility room did not have paper towels, paper towel dispenser or other method for staff to dry their hands. Observations were conducted on July 18, 2012 from 11:00 a.m. to 1:18 p.m., in the "Dirty" utility room with Staff #5. Staff #5 washed his/her hands at the sink in	T 175 T175 ①	① Failed to have adequate hand washing equipment in "dirty" room. This was corrected immediately by instructing maintenance / Construction personnel to install paper towel dispenser & alcohol dispenser. Also antibacterial soap was placed in the dirty room. ② . Once these items are installed, we will not be deficient again. Items will be replaced when they get low ③. The procedure will be that utility staff will inform administrator when items are low and those items will be replaced immediately. ④ Administrator will follow up with construction personnel to insure items are installed in a timely manner. Administrator will then check supply of these items weekly and replenish as necessary ⑤. Items will be installed and functional by 8/17/12 ~~[illegible]~~	

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T 175	Continued From Page 10 the "Dirty" utility room. Staff #5 did not have a method to dry his/her hands within the "Dirty" utility room. Staff #5 with wet hands left the "Dirty" utility room, walked approximately three (3) feet to obtain paper towel from the Scrub sink's paper towel dispenser. For each glove change thereafter, Staff #5 left the "Dirty" utility room to wash and dry his/her hands at the Scrub sink. [A "Dirty" scrub/utility room is a room designated to receive, clean and disinfect used instruments and or equipment following a procedure. After instruments are cleaned and disinfected in the "Dirty" scrub/utility room/designated area, they are taken to the "Clean" scrub/utility room/designated area where instruments are packaged and sterilized as appropriate for use again.] An interview was conducted on July 18, 2012 at 2:45 p.m. with Staff #1. Staff #1 acknowledged the need for the "Dirty" utility room to have adequate equipment for staff to dry their hands as part of hand hygiene and to prevent the spread of infection. 2. Observation and interview was conducted during the initial tour on July 17, 2012 at 9:28 a.m., with Staff #10. The observation revealed two (2) vacutainer plastic needle holders placed on a blood collection tube holder. Staff #10 reported to the surveyor the vacutainer needle holders were reused between patients. When asked about the process to distinguish "dirty" from "clean" vacutainer needle holders Staff #10 reported the vacutainer needle holders were used then placed back on the tube holder. Staff #10 reported there was no need to clean the vacutainer needle holders between patients. The observation revealed one of the vacutainer needle holders had visible dark red splatter within the hub, which attached to the needle to draw the patient's blood. Staff #10 was asked to observe	T 175	T175 ① Vacutainer needles were not disinfected between patients. This was corrected immediately by disinfected vacutainer needles between each patient. ② Nurse practitioner will recognize that disinfecting vacutainer needles between each patient is the requirement and will adhere to this requirement. ③ The process for disinfecting is spraying vacutainer needle with cavicide spray, letting it set for 3 minutes and then rinsing. This is done after each use. ④ Nurse practitioner will practice this process after each use and is the only staff member who draws blood. ⑤ This process is now in place and has been as of 7/19/12 - following inspection. This procedure is included in the policy on "processing of reusable medical equipment."	

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T 175	Continued From Page 11 the inner surface of the vacutainer needle holders hub, Staff #10 reported he/she did not have his/her glasses. Staff #1 was asked to observe the vacutainer needle holders; Staff #1 stated, "It says BD, I can't make out the rest." Staff #1 was asked to look inside the hub of the two vacutainer needle holders. Staff #1 stated, "That looks like blood in this one." A request was made for information that guided the facility's reuse without cleaning the vacutainer needle holders. An observation of the two vacutainer needle holders by a second surveyor was conducted on July 17, 2012 at 1:28 p.m. The second surveyor identified dark red splatter within the hub of one of the two vacutainer needle holders available for patient use. The facility did not have a policy or procedure for the reuse of vacutainer needle holders. The facility did not provide additional information or evidenced based information for the reuse with or without cleaning their vacutainer needle holders. Review of the manufacturer's information on line did not provide information that the product should be used more than one time [www.bd.com]. The manufacturer's information read "The BD Vacutainer (Trademark) Single-use Needle/Tube Holder is a quality, low-cost single use holder..." Observations were conducted on July 18, 2012 from 11:00 a.m. to 1:18 p.m., in the "Dirty" utility room with Staff #5. Staff #5 processed instruments, which needed to be autoclaved. Staff #5 left a pink sponge in the bottom of the sink. Staff #5 identified the sponge as "just a regular sponge". Staff #5 received the first jar after a procedure. Staff #5 removed the stopper from the procedure jar and ran water through the ports, where the suction hoses attached, used a toothbrush to scrub around the base of the ports	T 175	T175 cont. The process for reusing vacutainer needles is outlined in the "processing of reusable medical Equipment" policy. This policy is applies to all reusable equipment including the glass bottle and rubber stopper used in procedure. Staff #5 understands this process and is in compliance with this procedure. It is also understood that sponges can spread bacteria and are not considered reusable equipment.	

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T 175	Continued From Page 12 then placed the stopper in a basin of detergent/water. Staff #5 poured the blood, clots and other tissues from the procedure jar into the sink, and rinsed the jar with water. The sponge had contact with the blood, clots and tissues poured from the procedure jar. Staff #5 used a toothbrush to loosen blood and tissues from the inside of the procedure jar. Staff #5 acknowledged the toothbrush did not reach the bottom of the Procedure jar. Staff #5 stated, "I put the sponge in the jar and use the toothbrush to move the sponge around." Staff #5 retrieved the sponge from the bottom of the sink placed it in the procedure jar, added water and used the toothbrush to move the sponge around the inside bottom of the procedure jar. Staff #5 rinsed the procedure jar with additional water and placed the procedure jar in a basin with detergent/water. Staff #5 squeezed the water from the sponge and placed it on the sink lip. Staff #5 processed the other instruments used during to procedure: by rinsing them under running water, scrubbing with the toothbrush, and using his/her gloved hands to remove visible blood and tissue. Staff #5 changed gloves and removed the procedure jar, O-ring and stopper from the detergent/water placing the items on a disposable paper cloth. Staff #5 placed the stopper in the procedure jar and the O-ring over one of the stopper's suction port. Staff #5 did not spray the outside of the items with the disinfectant or let them air dry for three minutes as guided by the facility's policy/procedure. Staff #5 passed the items through a wall opening to the counter within the "Clean" utility room. Staff #5 removed his/her gown and gloves while in the "Dirty" utility room. Staff #5 entered the "Clean" utility room and prepared the procedure jar and stopper with a gauze sac attached to the stopper by an O-ring and placed the set up in the pass through window for the next procedure. Staff #5 cleaned the items	T 175		

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T 175	Continued From Page 13 from the next three procedures the same as the first. Staff #5 did not disinfect the sponge, toothbrush or the re-usable items (procedure jar, stopper, and O-ring) utilized during the procedures. An interview was conducted on July 18, 2012 at 3:40 p.m. with Staff #5 in the presence of Staff #1. Staff #5 reported he/she had not been aware that a sponge could spread infection and should not be utilized. Staff #5 acknowledged he/she did not spray the outside of the procedure jar, stopper or O-ring with the disinfectant. Staff #5 reported being unaware of the policy to spray the items with the disinfectant and allow them to air dry for three minutes prior to re-use. Staff #1 acknowledged Staff #5 had not followed the facility's policy related to cleaning re-usable equipment. A review of the facility's policy titled "Processing of Reusable Medical Equipment" conducted on July 17, 2012 read: "Purpose to prevent the spread of infection via reusable medical equipment by detailing levels of cleaning and disinfecting each type of equipment. Reusable equipment shall be cleaned, disinfected, and sterilized to prevent infection from spreading from patient to patient or to staff ... Procedure: ... e. Glass Bottles [Procedure jars] Spray with [Brand name of disinfectant]. Wait 3 minutes. Allow to air dry in Clean utility room. f. Rubber stopper Spray with [Brand name of disinfectant]. Wait 3 minutes. Allow to air dry in Clean utility room." According to the USDA Agriculture Research Service (ARS) newsletter dated February 2008 "...Sponges were soaked in 10% bleach solution for 3 minutes, lemon juice for 1 minute, or pure water for 1 minute, placed in a microwave oven for 1 minute at full power, or placed in a dishwasher for a full wash-dry cycle, or left untreated (control).	T 175		

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T 175	Continued From Page 14 Microwaving and dishwashing treatments significantly lowered bacterial counts compared to any of the immersion chemical treatments or the control. Counts of yeasts and molds recovered from sponges receiving microwave or dishwashing treatments were significantly lower than those recovered from sponges immersed in chemical treatments." According to ARS website Best Ways to Clean Kitchen Sponges - April 23, 2007 - News from the USDA Agricultural Research Service.mht read: "...treated each sponge in one of five ways: soaked for three minutes in a 10 percent chlorine bleach solution, soaked in lemon juice or deionized water for one minute, heated in a microwave for one minute, placed in a dishwasher operating with a drying cycle-or left untreated...They found that between 37 and 87 percent of bacteria were killed on sponges soaked in the 10 percent bleach solution, lemon juice or deionized water-and those left untreated. That still left enough bacteria to potentially cause disease. Microwaving sponges killed 99.99999 percent of bacteria present on them, while dishwashing killed 99.9998 percent of bacteria..." 3. Observation and interview conducted during the initial tour on July 17, 2012 at 9:28 a.m., with Staff #10 revealed only one chair in the laboratory area. Staff #10 reported the patients sat in the chair for blood draws testing for hemoglobin, Rh (Rhesus) factor, and serum pregnancy test if the sonogram was inconclusive. The observation revealed the right arm of the chair had an approximately 2.5 inch band of dark sticky residue. Staff #10 reported the residue was from placing tape on the arm of the chair. Staff #10 acknowledged the residue on the chair's surface prevented disinfection of the surface between patients.	T 175	T175 #3 Lab chair has been repaired and is free of tape residue. This was corrected on 8/1/12	

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T 175	Continued From Page 15 Observation and interview conducted during the initial tour on July 17, 2012 at 9:55 a.m., with Staff #10 revealed three (3) of three recovery room cots did not have intact surfaces. Staff #10 observed the tears on the sides and the top of the three cots that exposed the underlying foam cushion. Staff #10 reported if there was a spill of blood or other body fluids it could enter the exposed foam. Staff #10 stated, "Somehow these were missed by the re-upholster." Staff #10 acknowledged the three cots could not be disinfected between patients. 4. An observation during the initial tour July 17, 2012 at 9:58 a.m., with Staff #10 revealed a plastic container with a red blanket inside. Staff #10 reported the facility's laundry was processed by the parent facility in a different city and brought to the facility "every Wednesday." Staff #10 reported the staff from the parent facility transported the soiled linens after the procedure day was completed and brought clean linens the next week. An interview was conducted on July 17, 2012 at 3:48 p.m. with Staff #1. A request was made for information that ensured the facility's linens were washed at the proper temperature. Staff #1 reported he/she did not have the information and would contact the parent facility responsible for washing the linens. On July 18, 2012 at 8:39 a.m., Staff #1 presented the policy related to the processing, handling, storage, and transport of clean linens. Staff #1 reported he/she did not have information related to the whether the linen were washed at the correct water temperature of 160 degrees Fahrenheit. An interview was conducted on July 18, 2012 at approximately 2:15 p.m., with Staff #4. Staff #4 reported the washer had not been purchased that reached the required temperature. Staff #4 reported the facility should	T 175	T175 #4 We are currently only using disposable linens until our parent clinic acquires their new washer & dryer. At that time we will begin using linens from that facility, which will be accompanied by documentation stating temperatures linens are washed at, etc.	

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T 175	Continued From Page 16 be utilizing disposable linens. Staff #1 was not aware the facility was to use disposable linens. The facility did not have a policy /procedure related to the need to switch to disposable linens.	T 175		
T 180	12 VAC 5-412-220 D Infection prevention D. The facility shall have an employee health program that includes: 1. Access to recommended vaccines; 2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients; 3. An exposure control plan for blood-bourne pathogens; 4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; 5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection. This RULE: is not met as evidenced by: Based on interview and record review the facility's employee health program failed to have a written exposure control plan for blood borne pathogens or policies/procedures for compliance with U.S. Occupational Safety & Health Administration (OSHA) requirements and reporting workplace injuries and employee exposure to infections. The findings included Review of the facility's policies on July 17, 2012 did not reveal an employee health program plan,	T 180	T180 (1) Employee health program did not include criteria for reporting communicable disease to OSHA nor did it include a listing of potential communicable diseases + work restrictions should one come into contact w/ these. This was corrected immediately by including procedure for reporting communicable disease into the policy + procedure manual which is reviewed by all staff. (2) Since this has been included into the manual we will not be without it again. (3) Employees will follow the protocol outlined in the policy + procedure manual under "employee communicable diseases" (4) The administrator will monitor and ensure that the manual is maintained and that any changes are documented annually upon review. (5) This was immediately corrected + in place on 7/19/12	

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T 180	Continued From Page 17 policies or procedures for compliance with OSHA requirements. The facility did not have an exposure control plan for blood borne pathogens. The facility's policies and procedures did not include a process for reporting employee workplace injuries or employee exposure to infections. During an interview conducted on July 17, 2012 at approximately 3:35 p.m., Staff #1 reported he/she would check with the parent facility for additional information. An interview with Staff #1 conducted on July 18, 2012 at approximately 8:24 a.m. provided no additional information.	T 180	The administrator also printed and incorporated the OSHA forms for reporting work related injuries and illness to help guide someone through the process, should it arise.	
T 185	12 VAC 5-412-220 E Infection prevention E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow-up, and reporting activities: 1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop; 2. A procedure for surveillance, documentation and tracking of reported infections; and 3. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease. This RULE: is not met as evidenced by: Based on interview and record review the facility failed to have a procedure for the tracking infections. The findings included: Review of the facility's infection prevention plan	T 185	T185 OR did not have a method in place to track complication trends. We had a complication log but nothing showing changes / trends over time. This was corrected immediately by creating a line graph that tracks all complication logs and allows for visual data regarding changes in complications. (2) Now that there is a tracking device in place the administrator will compile all complications and enter them into tracking log. We should not be deficient again now that we have	

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T 185	Continued From Page 18 did not reveal the facility's methods or processes for surveillance, documentation and tracking infections. On July 17, 2012 at approximately 9:00 a.m., Staff #1 provided the surveyors a "Complication" binder. The "Complication" binder had one entry. An interview was conducted on July 18, 2012 at 10:08 a.m., with Staff #1. Staff #1 reported the facility did not have a system in place to track or trend infections. An interview with Staff #4 conducted on July 18, 2012 at 3:16 p.m. revealed the facility logged the complications but did not track or trend the occurrences/infections.	T 185	was tracked in place. ③. The procedure for tracking is that complications are documented in the complication log at the time of complication becoming known. Tracking of trends will occur over time as complication data is accumulated. ④. Administration will monitor the tracking on a monthly basis. At the end of each month, any complications will be tallied up and entered from tracking purposes. ⑤. This deficiency was corrected immediately and in place by 7/23/12	
T 315	12 VAC 5-412-300 A Quality assurance A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary. This RULE: is not met as evidenced by: Based on review of the Policy and Procedure Manual and interview with Staff #1, it was determined that no comprehensive plan had been implemented to develop a Quality Assurance Committee to access and evaluate the services of the facility as required in Section 12 VAC 5-412-300.A.	T 315	T315 ①No quality assurance policy + procedure was in the manual at the time of inspection. This was corrected immediately by adding the quality assurance info. to the manual. It was in place, just misplaced and not in its correct place within the manual.	

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T 315	Continued From Page 19 The findings included: 1. On July 17, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No policies and procedures to form a Quality Assurance Committee, to asses and improve services provided, a means of educating the staff and update polices and procedures . 2. Staff #1 acknowledged during interview that no policy and procedure had been developed to address the Quality Assurance Meeting. This interview occurred in the facility's office, on July 17, 2012, approximately at 4:10 p.m.	T 315	②The policy is in its correct placement within the manual and will remain there. ③. The policy/procedure is in place to allow for administrative personnel and staff to provide patient & employee safety and to identify potential problems. ④. QA meetings will be held a minimum of annually & include a physician, non physician health care provider administrator, and a staff member representing patient rights. ⑤This is currently in place as of 7/19/12.	
T 320	12 VAC 5-412-300 B Quality assurance B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance; 2. Supervision appropriate to the level of service; 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and 7. Staff concerns regarding patient care. This RULE: is not met as evidenced by: Based on review of the Policy and Procedure Manual and interview with Staff #1, it was determined that no policy and procedure were developed to ensure all the subjects of the Quality Assurance Committee would be addressed as required in Section 12 VAC 5-412-300.B.#1-#3 and #5-#7.	T 320	The QA policy also addresses that QA committee will meet annually (more if necessary) to address staff and patient issues. QA meeting minutes will be kept by administrator.	

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T 320	Continued From Page 20 The findings included: 1. On July 17, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No policy and procedure to list the subjects that would be discussed in the Quality Assurance Committee meeting as Staffing patterns and performance, Supervision appropriate to the level of service, Patient satisfaction, Complaint resolution, Infections, complications and other adverse events and Staff concerns regarding patient care. 2. Staff #1 acknowledged during interview that no policies and procedures were developed that would address the subjects that would be discussed in the Quality Assurance Committee Meeting. This interview occurred in the facility's office, on July 17, 2012, approximately at 4:15 p.m.	T 320		
T 325	12 VAC 5-412-300 C Quality assurance C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of: 1. A physician 2. A non-physician health care practitioner; 3. A member of the administrative staff; and 4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients. This RULE: Is not met as evidenced by:	T 325		

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T 325	Continued From Page 21 Based on review of the Policy and Procedure Manual and interview with Staff #1, it was determined that no policy and procedure were developed to address how problems would be addressed in the Quality Assurance Committee as required in Section 12 VAC 5-412-300.D. The findings included: 1. On July 17, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No policy and procedure to address how concerns would be addressed by the Quality Assurance Committee was available for review. 2. Staff #1 acknowledged during interview that no policy and procedure was developed that addressed the concerns and problems of the Quality Assurance Committee. This interview occurred in the facility's office, on July 17, 2012, approximately at 4:18 p.m.	T 325	T315, T320, T325, T335: ① All of these deficiency are addressing the lack of a QA policy & procedure but as stated on page 19, this was corrected immediately. ② The QA policy & procedure is present in the manual and will remain so. ③ Reference # for QA policy & procedure is 12 VAC 5-300-A, B, C, D, E. ④ Administrator will ensure QA committee meets a minimum of annually and will maintain meeting minutes ⑤ This is currently in place.	
T 335	2 VAC 5-412-300 E Quality assurance E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee. This RULE: is not met as evidenced by: Based on review of the Policy and Procedure	T 335		

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T 335	Continued From Page 22 Manual and interview with Staff #1, it was determined that no policy and procedure were developed to address the reporting of the results of the Quality Assurance Committee to the Governing Body as required in Section 12 VAC 5-412-300.E. The findings included: 1. On July 17, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No policy and procedure to address how the results of the Quality Assurance Committee would meet annually, and would self-assesses problems to ensure that a comprehensive review of the facility's program and what adverse events should be reported immediately was available for review. 2. Staff #1 acknowledged during interview that no policy and procedure was developed that addressed the reporting, analysis and data collected by the Quality Assurance Committee. This interview occurred in the facility's office, on July 17, 2012, approximately at 4:21 p.m.	T 335		
T 400	12 VAC 5-412-380 Local and state codes and standards Abortion faculties shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of	T 400		

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(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) COMPLETE DATE
T 400	Continued From Page 23 these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements. This RULE: is not met as evidenced by: Based on observation, interviews and record review the facility failed to meet the following requirements established in Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute: The findings included: Observations conducted on July 17, 2012 from 9:09 a.m. to 1:00 p.m. during the initial tour of the facility revealed: The facility did not have handicap-designated parking space(s). Access from the parking lot to the side walk required maneuvering over a curb/raised sidewalk edge approximately 3.5 inches in height. The facility's sideway did not have a wheelchair accessible grading. The front sidewalk had an uneven grading with an approximate 2.5-inch gap and raised area. Neither the building's front, back nor emergency exits were wheelchair accessible. Sterile supplies were kept on the bottom of an open cart in the "Clean" scrub/utility. The room did not have a visible system to monitor the temperature and humidity.	T 400	T400 We have spoken with the construction team and they have come in to assess the handicap accessible situation and the raised area/gap in the sidewalk. An architect visited the clinic on March 16, 2012. Sterile supplies have since been moved and a humidity gage is now in place in the "clean" utility room	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-0014	A. BUILDING _____ B. WING _____	07/18/2012

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T 400	Continued From Page 24 Sinks in the laboratory, "Soiled" scrub/utility and bathrooms had valves, which required the use of one's hands to turn on the water. The eyewash station was connected to the sink in a manner where it accessed hot water. The "Soiled" scrub/utility room served as the holding area for medical waste items awaiting transport. Staff #10 reported the blood/ tissue contaminated items used during procedures were placed in a biohazard red bag lined box. Staff #10 reported products of conception where placed in the same red box. Staff #10 reported the inner red bag was tied and the box was taped and remained in the "soiled" scrub/utility room for six days until pick up by the contracted medical waste transport company. Observation of the "Soiled" scrub/utility room did not reveal an exhaust ventilation system. The public corridor from the receptionist desk to the accessible bathroom and back door did not equal the required five feet width. The facility's record did not reveal an attestation from an architect that the building met the required (FGI) guidelines. The facility did not have documentation that the heating and cooling system provided two exchanges of outside air every hour. An interview and rounds was conducted on July 18, 2012 from 8:30 a.m. to 10:15 a.m. with Staff #11. The FGI workbook was reviewed with Staff #11 through questions and request for information/documentation of compliance. Staff #11 acknowledged the findings listed above. The above findings were discussed on July 18, 2012, at 3:16 p.m., with Staff #4. Staff #4 acknowledged the findings. No additional information was offered prior to the end of the survey.	T 400	Eye wash station was labeled with "hot" and "cold" identification and staff was educated about the different temperatures and proper usage. Ventilation was added to the "dirty" utility room on 7/22/12. Construction team has plans to removed water fountain to ensure five feet width in public corridor An architect visited the facility on March 16, 2012 Fire marshall / fire inspector visited the facility on 5/22/12 and 6/25/12 and deemed the facility to be in compliance with all codes.	

State of Virginia

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