

## Survey Findings/Facility Response

Facility : PLANNED PARENTHOOD - TEMPE

Survey Date - 9/11/2014 - Citation2

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### Survey Findings

Based on observation during facility tour, review of facility policy and procedures, documentation and manufacturer instructions for use (IFU), and interviews with staff, the Department determined the administrator failed to ensure the integrity of sterilization processes by failing to:

- (1). fully implement facility policy for routine weekly and monthly autoclave cleaning;
- (2). demonstrate consistent monitoring of sterilizer cycle temperature and pressure; and
- (3). demonstrate adherence to Planned Parenthood policy and manufacturer recommendations for operation and periodic maintenance of the facility's sterilizer.

sa200

sl276

slmult1

Findings include:

sa200

sl276

slmult1 1. Two (2) Surveyors observed during the facility tour 8/26/2014, that the Autoclave Log is

kept on a counter in Lab B.

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sa200

Review of facility policy "PLANNED PARENTHOOD OSHA MANUAL" reveals: "...Autoclave Cleaning Procedure...Quality control test (spore checks and/or cleaning cycles...) are to be performed weekly and the result logged on the autoclave log ...Monthly cleaning instructions...The autoclave must be cleaned at least monthly...Remember: MUST log all cleaning and spore check results on the Autoclave lognone ...."

Review of facility policy " THE PLANNED PARENTHOOD AUTOCLAVE LOG FORM" reveals: "... Weekly Autoclave Cleaning and Spore Check Log (Staff must initial once task has been completed)...Date...Cleaning...Monthly Cleaning ( Or after every 25 cycles...as per manufacturers [sic] instructions)...Date...Staff's initials...."

Review of the manufacturer's IFU "THE TUTTNAUER ELECTRONIC TABLETOP AUTOCLAVE OPERATION & MAINTENANCE MANUAL" (p. 49) reveals: "...clean every 20 cycles or as needed...."

Review of the most recently completed facility "AUTOCLAVE LOG" revealed that no weekly cleaning was documented on current log. The last documented monthly cleaning date was 6/27/2014.

The Surveyor requested documentation to demonstrate that the facility is tracking the number of cycles processed in order to determine cleaning frequency. None was provided

Employee #4 stated at interview 8/26/2014 at 11:30 a.m. that the weekly cleaning portion of the log was not being

filled out and that the facility processes approximately three sterilizer loads per day.

Employee #4 had been out of town and could not verify if the monthly cleaning had or hadn't been done in July because the log was not dated or initialed for July cleaning.

The Center Manager (Employee #10) verified 8/28/2014 at 12:03 p.m., that she had performed and documented the June monthly cleaning/initialed the log, and that no sterilization cleaning had been documented for the month of July.

2. Two Surveyors observed on tour at 10:25 a.m. 08/26/2014, that the Sterilizer Area in Lab B contained a Tuttnauer Electronic Tabletop Autoclave Model 3870 EA, equipped with a built-in printer. Surveyors further observed that a pink-lined white paper printout was curled up and lying on the lower shelf of the autoclave table. The name and/or initials of the staff who ran the sterilizer load were not noted on the printout. There was no additional paper loaded in the autoclave's empty paper printout cassette. The printout date of the last documented sterilizer cycle on the printout was 8/7/2014.

Surveyors also observed an unopened and unused roll of autoclave printout paper in a securely taped clear plastic bag on the Lab B countertop. The bag also contained the Operation and Maintenance Manual for the Tuttnauer Electronic Tabletop Autoclave Model 3870.

Review of facility policy "THE PLANNED PARENTHOOD OSHA MANUAL", Chapter 2 revealed: "...Sterilization Cycle...Proper temperature and exposure time must be achieved as indicated by sterilizer instructions...."

Review of the manufacturer's IFU "TUTTNAUER OPERATION & MAINTENANCE MANUAL FOR ELECTRONIC TABLETOP AUTOCLAVES, MODELS...3870...EA" revealed: "...Printer Operation...The autoclave is equipped with a character printer that prints a detailed history of each cycle performed by the instrument (for the record or for subsequent consideration)...The printing...contains the following information...Date and time of cycle start...Sterilization pressure...Sterilization temperature...Sterilization time...The data is printed from the bottom up, beginning with the program name and ending with 'O.K.' for a complete cycle, or 'FAIL' for an aborted cycle...."

Further review of the manufacturer's IFU "TUTTNAUER AUTOCLAVE MANUAL", page 27, revealed an example of a typical printout strip with an accompanying description of each item listed. The third line of the printout is listed as "Operator: \_\_\_\_\_," and the description "To be filled in manually by operator."

The staff tech (Employee #4) responsible for performing the sterilization procedures verified at interview 8/26/2014 that a refill paper roll had not been loaded in the sterilizer since the last documented load on 8/7/2014.

3. Review of facility policy "THE PLANNED PARENTHOOD OSHA MANUAL", Chapter 2, revealed: "...STERILIZATION...Sterilization completely kills or eliminates all microorganisms...All critical items need sterilization...HOW TO USE THE AUTOCLAVE...Autoclave Cleaning Procedure...Review specific autoclave manufacturer's instructions to ensure operational and cleaning compliance...Weekly cleaning instructions...Monthly cleaning instructions...Monthly cleaning instructions-Unless otherwise specified differently within the manufactures instructions...Remember: MUST log all cleaning...on the Autoclave log...."

Review of the manufacturer's IFU "TUTTNAUER OPERATION & MAINTENANCE MANUAL: ELECTRONIC TABLETOP AUTOCLAVES MODELS...3870...EA" revealed: MAINTENANCE INSTRUCTIONS...Preventive and Scheduled Maintenance...The maintenance operations described in this chapter need to be followed... Daily ...clean the door gasket with a mild detergent, water and a soft cloth or sponge...The gasket should be clean and smooth... Weekly ... ONCE PER WEEK , clean the air jet...To ensure that the temperature inside the chamber rises properly it is necessary to keep the air jet clean...Clean the water sensor in the rear of the chamber with a damp cloth or sponge...Once per week clean and descale the chamber, copper tubes and the reservoir using Chamber Brite ...Clean the tray holder and trays...Put a few drops of oil on the...door...Clean the outer parts of the autoclave with a soft cloth...Periodically...Once every month clean and check the safety valve...Clean every 20 cycles or as needed....

Employee #4 stated at interview during the facility tour 8/26/2014 at 11:30 a.m., that in approximately April of 2014, the facility installed a new Tuttnauer Electronic Tabletop Autoclave in Lab B.

Employee #4 confirmed that he is responsible for cleaning the autoclave, that the sterilizer is used on a regular basis, and that approximately three loads per day are processed.

Employee #4 stated that he had not yet opened the Tuttnauer Operation & Maintenance Manual for the new sterilizer, and that he assumed that the required cleaning products and procedures were the same with the new sterilizer as they had been with the previous Pelton and Crane unit.

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## **Rule/Statute**

R9-10-1028. Infection Control

An administrator shall ensure that:

3. Policies and procedures are established, documented, and implemented to protect the health and safety of a patient that cover:

a. If applicable:

iii. Sterilization and disinfection of medical equipment and supplies;

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## **Facility Response**

The date (10/23/2014) represents when the facility corrected the citation and was confirmed by the Department to be back in compliance. A facility is required to submit a Plan of Correction (POC) for each citation identified during a survey. This Plan of Correction describes how the facility is going to make corrections, the facility representative responsible for making the corrections, and what systems are in place to prevent recurrence. Once the facility has submitted an acceptable Plan of Correction, the Department confirms that the citation is corrected.

For a copy of the Plan of Correction, please contact the facility or the Department of Health Services.