MedPlast
Innovative Solutions for Healthcare

Dear Ms. Lazzaro,

MedPlast Medical, Inc. (MedPlast) received a Violation Notice (VN), dated July 25, 2018, for its facility located at 520 Watson SW, Grand Rapids, Michigan.

The Violation Notice specifically indicated the following Rule/Permit Condition Violations:

Process Description	Rule/Permit Condition Violated	Comments
Sterilization Chamber Vents and/or Aeration Chamber Vents	40 CFR Part 63, Sub-art O (40 CFR 63.362)	Failure to maintain a 99 percent emission reduction from the sterilization chamber vents and/or the aeration room vents as required.
EUETOSTERILIZERS	PTI No. 605-89B, EUETOSTERILIZERS, Speciation Condition 1.5	Failure to maintain a minimum capture and destruction efficiency of 99.5 percent by weight for Ethylene Oxide as required.

The VN requested that MedPlast submit a written response to the VN by August 15, 2018. On August 13, 2018, MedPlast requested and received approval for an extension until August 24, 2018. This letter serves as the written response.

Response to Violations

The underlying issue behind the cited violations of Ethylene Oxide emissions from the EUETOSTERILIZERS not being adequately captured and controlled was first identified in July of 2017. At that time, one of the sterilizer chambers malfunctioned and resulted in excess fugitive emissions. This issue was self-identified by MedPlast and brought to the attention of the MDEQ through a 10-day report submitted by MedPlast on August 17, 2017. A brief recap of that issue is provided below:
After investigating the cause of the leak in Chamber C, it was determined that the door had experienced a failure resulting from wear due to the execution of a positive pressure cycle run in that chamber.

The positive pressure cycle is an ethylene oxide sterilization cycle that is run with the chamber pressure being higher than atmospheric pressure during the exposure phase (positive pressure cycle; Cycle 330). This pressure results in an outward force on the chamber door. Loads sterilized utilizing positive pressure cycles are at risk of leaking and maintain a higher volume of residual ethylene oxide that off-gas into the facility contributing to the fugitive emissions.

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At the conclusions of our investigation, the following measures were taken to control air pollution and minimize emissions:

- *Execution of Cycle 330 in Chamber C was immediately stopped indefinitely until the root cause and corrective actions could be determined. July 20, 2017*
- *The Chamber C door gasket was replaced on July 22, 2017 and it was pressure/vacuum tested with passing results on July 25, 2017.*
- *After completion of the repairs, the decision was made not to resume executing Cycle 330 in Chamber C in order to prevent any possible risk of future emissions.*

Corrective actions were taken to prevent future occurrences of the malfunction, but the review of the incident highlighted that one of its sterilization cycles was an on-going source of higher amounts of fugitive emissions. The following actions were initiated to address this:

1. All product that could withstand a negative pressure cycle were to be transitioned to a new validated negative pressure cycle.

As a result of the above actions, the monthly losses of fugitive emissions decreased from a peak of 404 pounds per month at the time of the August 2017 10-day report, to the most current data of 34 pounds which represents the month of July 2018. This demonstrates a reduction of 91% based on actions already taken. This reduction was sufficient to bring the facility into compliance with 40 CFR Part 63, subpart O (99% emission reduction) but not with PTI No. 605-89B, special condition 1.5 (99.5% minimum capture and destruction efficiency).
Our current performance can be further characterized in the following manner:

- Our current 12 month rolling average demonstrates that our capture and destruction efficiency operates within a range of ***98.9 to 99.7*** for efficiency.
- July, 2018 demonstrated 99.7% efficiency.

MedPlast is fully committed to further reduction of fugitive emissions in order to drive overall capture and destruction efficiency as high as possible and provide sustainable performance that meets the 99.5% requirement.

The limited operation of positive pressure cycles to further reduce the site's fugitive emissions still represents the biggest opportunity for improvement. Therefore, MedPlast has collaborated

with our customer(s) to identify specific steps that can be taken to further reduce and eliminate the targeted cycle that is estimated to have the largest impact on our fugitive emissions.

- Actions Already Completed:
  - An alternate negative cycle was identified and many products previously run on the positive cycle were transitioned over. This action was completed as a correction coming out of the 2017 10-day report. This resulted in a 75% reduction in the number of positive cycles run.
- Steps taken upon July, 2018 violation receipt:
  - Additional scheduling changes were made by the customer and internal cycle designations were modified to further reduce the product codes that remain on the positive pressure cycle. This resulted in a further 50% reduction of number of loads/week being processed under the positive pressure cycle (now 1-2 loads/week).

- Further Actions To Be Taken:
  - 30% of the remaining product codes will be transitioned to a negative cycle with evaluation of this transition plan and timing to be determined in coordination with our customer on or before September 11, 2018, with implementation completed by February, 2019. This should result in an additional 50% reduction of total loads resulting in 1 load/week.
  - For all other remaining product codes, the customer has committed to working with MedPlast to either identify a suitable negative pressure cycle or transition those product codes to an alternate sterilization methodology. The timeline for total elimination is currently under evaluation as the customer must first understand what sterilization method will be used and the scope of sterilization validation activities. However, as we work through these activities, the customer will at that point be operating 1 load/week of the positive pressure cycle. MedPlast is confident that while we work through any additional sterilization validations, the site will be operating consistently above the required 99.5% efficiency.

We fully expect that these actions will be sufficient to bring the operations into compliance and will be monitoring the emissions on a monthly basis to verify that is the case. We also will analyze any future sterilization cycles for the likelihood of fugitive emissions prior to putting them into practice.

Please let us know if you have any questions or require any additional information relative to the above action plans.

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The Violation Notice indicates that MedPlast will conduct stack testing of the system prior to November 30, 2018. In a follow-up meeting held with members of the MDEQ on August 8, 2018, MedPlast discussed that additional internal review would be required for determination and timing, if applicable, around the execution of stack testing with the MDEQ. MedPlast will prepare a response for the plans that will be shared with the MDEQ on or before September 28, 2018.

Additionally, the MDEQ requested a facility-wide Potential to Emit demonstration be completed for the stationary source. This work is under way and will be completed no later than September 28, 2018.

Bryan Curry
Sr. Director Quality Assurance and Regulatory Affairs
MedPlast Medical, Inc.