**MEMORANDUM**

Date: 7/20/2023

Subject: Medtronic's Villalba Facility
Addendum to the Clean Air Act Inspection Report

From: Alex Rivera, Senior Environmental Engineer
Air Protection Team
Multimedia Permits and Compliance Branch

ALEX RIVERA
Digitally signed by ALEX RIVERA
Date: 2023.07.21 10:36:20 -04'00'

Through: Nancy Rodríguez, Chief
Multimedia Permits and Compliance Branch *for*

JOSE RIVERA
Digitally signed by JOSE RIVERA
Date: 2023.07.21 12:35:09 -04'00'

To: Medtronic's Villalba Facility File

**Background**:

On November 21, 2022, I performed an inspection of the referenced Facility owned and operated by Medtronic in the municipality of Villalba, Puerto Rico. On January 20, 2023, an inspection report (the "Inspection Report") was signed and submitted to Medtronic ("Medtronic" or the "Company").

On February 1, 2023, representatives from Medtronic and EPA's Multimedia Permits and Compliance Branch ("MPCB") held a technical meeting (the "Meeting") to discuss the contents of the Inspection Report. During the meeting, Medtronic was represented by Mr. Elvin Vélez, Mr. Billy Laboy and Mr. Bob Kreye, and I represented MPCB.

**Purpose of this Memorandum**:

The purpose of this Memorandum is to summarize the discussions held during the Meeting and to document statements and clarifications made by Medtronic to the Inspection Report:

1. I informed that EPA does not, as a general practice, conduct this type of meeting to discuss the contents of an inspection report.

2. The Company's representatives indicated that they intended to clarify during the meeting a series of statements made in the Inspection Report. Then, they went to say that the number of sterilizers operating in the Facility's south building are six (6) and that the Facility has six (6) abators in operation. Medtronic's representative also stated that the Inspection Report implies that the Facility had seven (7) sterilizers instead.

3. I was informed that catheters are not sterilized using EtO and that the Inspection Report implies that the catheters are sterilized with EtO.

4. The Company's representatives indicated that project completed in the Medtronic's facility in Jacksonville, Florida, is "similar" rather than "same", as indicated in the Inspection Report.

5. The Company's representatives explained that catheters should be replaced by leads when referring to low voltage EtO sterilization.

6. Medtronic claimed that the Inspection Report statement about lack of a standard operating scenario could be interpreted as not having a required procedure.

7. The Company's representatives indicated that the abator catalytic material is replaced every four (4) years rather than every three (3) years, as stated in the Inspection Report. I indicated that my inspection notes reflect that I was told that the catalytic material is replaced every three (3) years.

8. The Company's representatives claimed that the EtO consumption values should be verified and agreed on providing the correct values.

9. I indicated that the EtO consumption tables that were provided during the Inspection did not specify the units, and that companies usually provide these values either in pounds or tons.

10. The Company's representative informed that because the Facility's cartridges have 127 grams, the Company tracks its consumption in grams.

11. I was informed that the EtO consumption values in tons, which were included in the Inspection Report, are not accurate. I acknowledged my incorrect interpretation of the EtO consumption logs and understood the rationale presented by Medtronic's representatives. They indicated that the correct EtO consumption values are the following:

    a. 2020 EtO consumption – 5,161.79 pounds or 2.58 tons (the Inspection Report incorrectly included a consumption of 7.07 tons).
    b. 2021 EtO consumption – 2,495.50 pounds or 1.25 tons (the Inspection Report incorrectly included a consumption of 9.16 tons).
    c. 2022 EtO consumption – 2,543.38 pounds or 1.17 tons (the Inspection Report incorrectly included a consumption of 4.5 tons).

12. The Company's representatives informed that the power cogeneration unit (Combine Heat and Power) will not be operated by Medtronic and that the permit is not under Medtronic's ownership. They indicated that the responsible party for the cogeneration unit permit is a third party.

13. I was informed that the catheters are sterilized using gamma by a company in Aguadilla, Puerto Rico.

14. I was informed that the Facility only uses the abator outlet to measure EtO concentrations and that the inlet test port is not used for any purpose, which clarifies a statement in the Inspection Report that indicates that the inlet test port is used for measuring EtO concentrations.

15. The Medtronic's representatives shared a PDF version of the Inspection Report that depicts their comments. I explained that we do not redact or edit inspection reports once finalized but will consider adding a memorandum to the facility record summarizing their recommendations.

This memorandum becomes an addendum to Inspection Report and should be kept in EPA's Medtronic files for the Facility.