



GEORGIA

DEPARTMENT OF NATURAL RESOURCES

ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

Air Protection Branch

4244 International Parkway
Suite 120
Atlanta, Georgia 30354
404-363-7000

August 10, 2020

Submitted electronically to KBroadley@chemence.com

Dr. Kenneth Broadley
Chief Regulatory & Quality Officer
Chemence Medical, Inc.
200 Technology Drive
Alpharetta, GA 30005

RE: Request for Air Toxics Assessment
Chemence Medical, Inc.

Dear Dr. Broadley:

The U.S. Environmental Protection Agency has determined that ethylene oxide is a carcinogen and has updated their risk calculations. The Division recently sent a request for information to facilities such as yours that potentially use ethylene oxide in the medical products industry. Your response to the information request indicated that your facility conducts sterilization using ethylene oxide, using 627 grams per use three days per week. Additional information was also provided showing testing your facility had conducted indicating that the facility's indoor air quality is well within the current OSHA permissible exposure limit. However, the OSHA limit is not directly comparable to the concentrations modeled or measured at the closest residences to your facility. Additional information is necessary to evaluate your current operation's risks due to ethylene oxide use and to establish any necessary restrictions in order to ensure no elevated risk at nearby residences is caused by the usage.

Section 391-3-1-.02(2)(a)(3) of the Georgia Air Rules for Air Quality Control provides that, notwithstanding any other emission limitation or other requirement in the regulations, more stringent emission limits or other requirements may be required of a facility as deemed necessary by the Director to (i) meet any existing Federal laws or regulations; or (ii) to safeguard the public health, safety and welfare of the people of the State of Georgia. Although your facility's emissions may be too low to trigger permitting requirements, the Director hereby invokes this authority to request a detailed Air Toxics Ambient Impact Assessment for your facility.

Within 60 days of receipt of this correspondence, please submit a detailed Air Toxics Ambient Impact Assessment following the current Georgia Guideline for Ambient Impact Assessment for Toxic Air Pollutants. Guidance for these requirements can be found at: <https://epd.georgia.gov/air-protection-branch-technical-guidance-0/air-quality-modeling>.

Should the Air Toxics Assessment indicate no elevated risk from the facility, emissions testing must be performed as soon as practicable, but no later than December 1, 2020, in order to confirm any assumptions

made in the air toxic model. A test plan must be provided to the Division at least 30 days prior to the date of the testing, and a 30-day prior written notice of the test date and time must be provided to the Division in order to afford us the opportunity to witness and/or audit the test.

Should the Air Toxics Assessment indicate an elevated risk from the facility, a permit application must be provided to the Division within 30 days of completion of the Air Toxics Assessment showing excess risk. The permit application will be required to include an emissions control system installed on ethylene oxide sterilization operations to reduce ethylene oxide emissions from the facility. This application must also include updated modeling showing that the added controls lower the risk to an acceptable level. A schedule for installation of the equipment and subsequent testing on the installed equipment effectiveness should be included with the application. The control equipment shall be installed as soon as practicable, but no later than January 31, 2021. Testing to verify the effectiveness of the control system would then be required within 90 days of installation. The test plan and written notice referenced above would also be required within the specified timelines.

For any questions or more information regarding this letter, please contact Stephen Damaske at (404) 363-7067 or stephen.damaske@dnr.ga.gov. For questions about the permitting process, please contact Heather Brown at (404) 362-2511 or heather.brown@dnr.ga.gov. For questions about the toxic impact modeling, please contact Byeong Kim at (404) 362-4851 or at Byeong.Kim@dnr.ga.gov.

Sincerely,



Sean Taylor
Program Manager
Stationary Source Compliance Program

SMT:sgw