

## HEARING OFFICER'S REPORT

**TO:** The Honorable Shawn M. Garvin  
Cabinet Secretary, Department of Natural Resources and Environmental Control

**FROM:** Theresa L. Smith  
Regulatory Specialist, Office of the Secretary  
Department of Natural Resources and Environmental Control

**RE:** Natural Minor Construction Permit Application of Noramco Inc.

**DATE:** February 28, 2024

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### **I. BACKGROUND AND PROCEDURAL HISTORY:**

A virtual public hearing was held on Tuesday November 7, 2023, at 6:00 p.m. via the State of Delaware Zoom Platform by the Department of Natural Resources and Environmental Control (“DNREC,” “Department”) to receive comment on the application submitted by Noramco, Inc. (“Noramco,” “Applicant”) for a Natural Minor Construction Permit to install a new vacuum pump and add a new production line for two new products at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County (“Application”) in accordance with 7 DE Admin. Code 1102 - *Permits* (“Regulation”). Pursuant to 7 *Del.C.* Ch. 60, facilities are required to obtain air quality permits for equipment that has the potential to discharge air contaminants into the atmosphere.

On April 13, 2023, the Department’s Division of Air Quality (“DAQ”) received the initial application to install a new production line for two new products. The new production line will manufacture “D8” and “D9” that are intermediates for a medication prescribed to support patients undergoing treatment for cancer, HIV, and anorexia. After submitting the initial application, the Department received a revised Application on July 17, 2023, and then additional revisions were received on August 14, 2023. The revised application added the installation of a new vacuum pump, as the existing equipment in the facility would not be able to support the new production line. It should be noted that in accordance with 8 DE Admin Code 900, Section 6, the Applicant submitted a request for confidentiality of records to safeguard propriety

information and trade secrets contained within the Application. Therefore, the report will only include publicly available information.

Noramco is a pharmaceutical manufacturing facility that specializes in producing batches of pharmaceutical intermediates that are the active ingredients for various medications that treat a variety of conditions including ADHD, pain, addiction treatment, opioid overdose, and nausea. Pharmaceutical intermediates are chemical compounds produced during the synthesis or manufacturing process of pharmaceutical drugs. They are precursor molecules that undergo further chemical reactions to eventually form the active pharmaceutical ingredients or final drug products. These intermediates serve as building blocks for the creation of various medications.

Noramco is considered a major source and operates under a Facility-Wide Title V Permit, Permit #AQM-003/00324 – Renewal (1) Revision (2). A major source facility emits or has the potential to emit any criteria pollutant or hazardous air pollutant (“HAP”) at levels equal to or greater than the Major Source Thresholds (“MST”) set in the *Clean Air Act* (“CAA”.) Noramco’s Facility-Wide Title V Permit limits their annual rolling 12-month total emissions to 20.1 tons per year of VOC, 10.7 tons per year of combined HAPs, and 9.9 tons per year of individual HAPs. The New Castle County MST for volatile organic compounds (“VOC”) and HAPs, is 25 tons per year for each and 10 tons per year for individuals HAPs. It should be noted that Noramco is not requesting an increase to Facility Wide emissions as part of this application.

As previously stated, the Applicant’s proposed project entails the installation of a new vacuum pump and a new production line for the manufacturing of D8 and D9. The production process of D8 and D9 result in the release of air pollutants such as VOC and HAPS into the atmosphere. Specifically, the individual VOCs and HAPs emitted include Ethanol, Ethyl Acetate, Methanol, n-Butanol, Tetrahydrofuran, Toluene, Triethylamine, Acetone, and Hydrogen Chloride. The total potential emissions from the manufacturing process of both D8 and D9 are approximately 4.9 tons/ year of VOCs and 2.6 tons/year of HAPs. It’s important to note that this estimation is calculated before considering the implementation of any control devices, also known as uncontrolled emissions.

Controlled emissions are measured using devices that work to prevent pollutants from entering the atmosphere. The manufacturing process for D8 and D9 include one of two control devices, a Caustic Scrubber that has a 93% (emission) destruction efficiency or VARA Carbon Adsorber that has a 95% (emission) destruction efficiency. The calculated controlled emissions using one of the two devices is measured at 0.50 tons/year of VOCs and 0.22 tons/year of HAPs, for both D8 and D9 combined.

The Applicant's total emissions for facility-wide production measured 1.5 tons of VOCs and 0.55 HAPs in 2021, and 1.48 tons of VOCs and 0.88 HAPs in 2022. The actual emissions for both years were lower than their Title V Permit limits (20.1 tons per year of VOC, 10.7 tons per year of combined HAPs.)

As a part of the application review process, the Department's DAQ performed AERSCREEN Dispersion Modeling analysis. This model estimates a maximum downwind concentration ("MDC") of a pollutant from a source. The MDC value is then compared to an established threshold limit value ("TLV") exposure limit. A TLV represents the airborne concentrations of pollutants that individuals are exposed without experiencing adverse health effects. The Department applies a safety factor of 100 to account for different ages, health conditions, genders, and body types. To ensure public health, safety, and welfare are not negatively affected by the proposed project, the ratio of TLV to MDC should exceed 100:1.

Based on the AERSCREEN Dispersion Modeling analysis, Department's DAQ concluded that the emissions of individual VOCs and HAPs resulting from the manufacturing D8 and D9 are above the 100:1 threshold. Therefore, it is presumed that the emissions will not adversely impact public health, safety, and welfare.

The Department placed the revised application on public notice on August 20, 2023. To that, the Department received correspondence from the public in objection to the revised application and a public hearing was requested. In addition to scheduling a hearing the Department scheduled a public information session on the proposed Application.

The Department held a Community Information Session on Tuesday, October 24, 2023, from 6:00 PM to 7:00 PM at 1113 E 7th St., Wilmington, DE 19801 and offered virtual attendance to the event as noticed in the Wilmington News Journal and Delaware State News on October 1, 2023. The purpose of the meeting was to provide the public an opportunity to ask questions about the proposed project and for the Department and Applicant to respond, in the same. At the conclusion of the meeting the Department offered the public various ways to submit comment for the record being generated in this matter.

On November 7, 2023, the virtual public hearing was held by the Department. There were seventeen (17) members of the public in attendance at the virtual hearing, along with the Applicant and DAQ staff. The record remained open through November 22, 2023, and comment was received from the public. Subsequent to the record closing, this Hearing Officer requested a Technical Response Memorandum (“TRM”) from the expert staff of DAQ and will be discussed in further detail below. Proper notice of the hearing was provided as required by law.

## **II. SUMMARY OF THE PUBLIC HEARING RECORD:**

The public hearing record (“Record”) consists of the following documents: (1) a verbatim transcript; (2) seven (7) documents introduced by responsible Department staff at the public hearing held on November 7, 2023 and marked by this Hearing Officer accordingly as "Department Exhibits 1-7"; (3) one (1) document submitted by Dave Tennett, Maintenance, Engineering, Information Technology, and Environmental, Health, & Safety for Noramco Inc., and marked by this Hearing Officer as "Applicant Exhibit 1"; (4) the TRM from Noura Abualfaraj, Environmental Engineer, Division of Air Quality; and (5) the revised draft Permit-APC-2023/0086-CONSTRUCTION (VOC RACT) prepared by the Department’s DAQ regarding Noramco Inc.’s Natural Minor Construction Permit Application. The Draft Permit is expressly incorporated into this Report and attached hereto as Appendix “B”. The Department's person primarily responsible for reviewing this Natural Minor Construction Permit Application, Noura Abualfaraj, also developed the Record with the relevant documents in the Department's files.

Presenting for the Application at the hearing was Dave Tennett with Noramco. Following opening remarks from Ms. Abualfaraj on behalf of the Department (and the introduction of the Department's exhibits to be entered into the Record), Mr. Tennett, proceeded to offer a brief background of Noramco and provided an overview of the project as proposed in the revised Application. Mr. Tennett concluded the presentation on behalf of the Applicant with the request to submit the visual presentation as an exhibit. The Record closed with regard to public comment 15 days following the public hearing, on November 22, 2023.

Subsequent to the close of the Record as noted above, this Hearing Officer requested a TRM from the DAQ's technical experts to: (1) address the concerns associated with this pending Application, as set forth in the public comment received by the Department; (2) provide a formal regulatory review of the Applicant's proposed project; and (3) offer the DAQ's conclusions and recommendations with regard the pending Application for the benefit of the Record generated in this matter.

The Department's TRM, attached hereto as Appendix "A," acknowledges the ten comments received from the public concerning the proposed Application, and provides a thorough and balanced response to the same, accurately reflecting the Record generated in this matter. Rather than attempting to relay each of the public comments received in this matter, this Order will highlight the Department's responses to the same, as provided for in full within the Report's Appendices, as referenced above.

The Department's TRM addresses the concerns of environmental and public health impacts, safety protocols, and public engagement. The Department received numerous comments regarding the public health impacts of the proposed project. The data provided above calculated emissions for each pollutant that will be emitted from the manufacturing of D8 and D9. The AERSCREEN Dispersion Modeling conducted by the Department provided analysis resulting in TLV-to-MDC ratios above 100:1 and it is presumed that the emissions will not negatively impact the public health, safety, and welfare. In addition, the Department referred to the cancer and non-cancer risk data developed by Environmental Protection Agency's (EPA) Air Toxics Screening Assessment for the area Noramco is located. The location shows that the risk

is considered lower (30 in 1,000,000) than the EPA's upper limit of acceptable risk (100 in 1,000,000.)

Furthermore, the Applicant is limited by their Title V permit to 20.1 tons per year of VOC, 10.7 tons per year of combined HAPs, and 9.9 tons per year of individual HAPs. The Department confirmed that the analysis conducted by the Applicant with adding the production of D8 and D9 to their manufacturing process of other pharmaceuticals does not exceed the permitted limit amount. Additionally, to clarify the concern regarding the Carbon Monoxide (CO) and Carbon Dioxide (CO<sub>2</sub>), the Department provided that the facility-wide CO and CO<sub>2</sub> emissions are not impacted by the proposed project. However, it was noted that the emissions recorded for 2021 and 2022 were below the permitted levels.

Other concerns were raised regarding the safety protocols in place to protect the surrounding community. The facility operates under a Title V permit and is required to report any discharge more than any permit limits to the Department's 24-hour Environmental Emergency Notification and Complaint line, in accordance with Condition 3(c)(2) of Permit: AQM-003/00324 (Renewal 1) (Revision 2.) In addition, Noramco is subject to Tier II Emergency Planning and Community Right-To-Know requirements, as well as the regulations governing hazardous waste.

Finally, in response to the request for public engagement, the Department scheduled a community information session to provide a platform for public engagement with the Department and Applicant, prior to the scheduled hearing. This meeting provided the opportunity for the public to address concerns and questions, and for the Department and Applicant to provide detailed responses, in the same. Furthermore, the Department also amended the proposed draft permit to include stipulations for the Applicant to form a "Community Advisory Board," thus providing the community with communication amongst stakeholders and the public.

In conclusion, DAQ drafted the permit, and subsequently made revisions, in accordance with applicable state and federal laws, ensuring its effectiveness in the protection of human health, welfare, and the environment.

I find that the DAQ's TRM offers a detailed regulatory review of all aspects of the Applicant's proposed revised Application, identifies all the concerns raised by the public and responds to them in a balanced manner, with accurately reflecting the information contained in the Record. Thus, the TRM and revised draft permit is attached hereto as Appendix "A" and Appendix "B", respectively, and expressly incorporated herein as such.

### **III. RECOMMENDED FINDINGS AND CONCLUSIONS:**

The Applicant has applied for a Natural Minor Construction Permit, seeking approval to install a new vacuum pump and add a new production line for two new products (D8 and D9) at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County. I find that the Applicant's proposed revised Application meets the requirements established in the Regulations.

In reviewing the applicable statutes and regulations, the Department's experts in the DAQ have concluded that the aforementioned project complies with all applicable federal and state laws and regulations. Should this Application be approved, the Natural Minor Construction Permit that would be issued by the Department would be reflective of the revised Application submitted and would include all necessary requirements intended to protect public health and the environment. I find that the Applicant has adequately demonstrated its compliance with all requirements of the statutes and regulations, as noted herein, and that the record supports approval of the Application submitted by the Applicant.

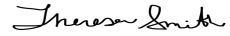
In conclusion, I recommend that the Natural Minor Construction Permit necessary for the proposed project as set forth in the revised Application submitted by the Applicant consistent with the Record developed in this matter, be issued by the Department in the customary form, and with appropriate conditions.

Further, I recommend the Secretary adopt the following findings and conclusions:

1. The Department has jurisdiction under 7 *Del.C.* §§6003, 6004, 6006(4) and all other relevant statutory authority, to make a final determination of the Application after holding a public hearing, considering the public comments, and reviewing all information contained in the Record generated in this matter;
2. The Department provided proper public notice of the Application submitted by Noramco Inc., and of the public hearing held on November 7, 2023, and held said hearing to consider all public comment that may be offered on the Application, in a manner required by the law and regulations;
3. The Department has carefully considered the factors required to be weighed in issuing the permit required by this Application, and finds that the Record supports approval of the Application and the issuance of the Natural Minor Construction Permit associated with the same;
4. The Department shall issue the Natural Minor Construction Permit to the Applicant, Noramco Inc., to install a new vacuum pump and add a new production line for two new products (D8 and D9) at their facility located at 500 Swedes Landing Road, Wilmington, DE in New Castle County, consistent with the Record developed in this matter. Furthermore, said permit shall include all conditions as set forth in the Department's draft permit, to ensure that Delaware's environment and public health will be protected from harm;
5. The Department has an adequate Record for its decision, and no further public hearing is appropriate or necessary; and



6. The Department shall serve and publish its Order on its internet site and shall provide legal notice of the Order in the same manner that the Department provided legal notice of the Application.



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Theresa L. Smith  
Public Hearing Officer

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Attachments/Appendices:

Appendix A: Technical Response Memorandum (January 3, 2024)

Appendix B: revised Draft Permit for Noramco Inc.

Permit #APC-2023/0086-CONSTRUCTION (VOC RACT)