TO:	Theresa L. Smith
	Hearing Officer

THROUGH: Angela D. Marconi, P.E. Division Director

> Amy S. Mann, P.E. Program Administrator

FROM: Noura Abualfaraj, PhD

SUBJECT: Technical Response Memorandum for Noramco Inc. Permit Application to Install a Vacuum Pump and Manufacture Two New Products (D8 and D9) Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u>

DATE: January 3, 2024

BACKGROUND

Theresa Smith, Public Hearing Officer, requested a Technical Response Memorandum (TRM) to provide expert technical assistance for the Hearing Officer's Report and recommendations to the Secretary with regard to the pending construction permit application to install a new vacuum pump and manufacture two new products at Noramco's 500 Swedes Landing Road facility in Wilmington, Delaware.

Detailed below are the Department of Natural Resources and Environmental Control's (DNREC or the Department) Division of Air Quality's (AQ's) responses to the comments provided during the November 7, 2023, Virtual Public Hearing and the comments received prior to the November 22, 2023, closing of the administrative public hearing record for Noramco's proposed activity.

A public hearing was held on Tuesday, November 7, 2023, to consider comments from the public on an application submitted by Noramco Inc. requesting a construction permit to install a new vacuum pump in Plant 3 and add a new production line for the manufacturing of two new products, "D8" and "D9", at their 500 Swedes Landing Road, New Castle County facility by **Permit:** <u>APC-2023/0086-</u> <u>CONSTRUCTION (VOC RACT)</u>.

Prior to the public hearing, a community information session was held on Tuesday, October 24, 2023. The Community Information Session allowed the Department and Noramco to engage with the public and provided the public with the opportunity to ask questions about this project. Questions and comments received at the Community Information Session are not part of the public hearing record.

REVIEW OF APPLICATION AND PUBLIC HEARING

The 7 **DE Admin. Code** 1102 Construction Permit Application was originally received by AQ on April 13, 2023. Noramco later amended the application to include the installation of a new vacuum pump as the existing vacuum pump would not be able to support the proposed project. The revised application was received on July 17, 2023, and additional revisions were received on August 14, 2023. A public notice was issued, and the application was advertised on August 20, 2023, in the **News Journal** and the **Delaware State News** for 15 days.

MEMORANDUM Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 2

The Department received a request for a public hearing on September 2, 2023. The public hearing was then scheduled and advertised on October 1, 2023, in the **News Journal** and the **Delaware State News**. The Department also scheduled a Community Information Session which was held on October 24th, 2023, and was advertised along with the public hearing notice. A virtual public hearing was held on November 7, 2023. The public comment period remained open for 15 days after the hearing and closed on November 22, 2023.

On behalf of DNREC, Hearing Officer Ms. Theresa L. Smith, conducted the public hearing. AQ's Environmental Engineer, Noura Abualfaraj, presented an overview of the facility and proposed project, and provided information on the air permitting actions that would be associated with the construction permit application.

Mr. Dave Tennett, Director of Maintenance, Engineering, Information Technology, and Environmental, Health, & Safety at Noramco, presented an overview of the proposed project on behalf of the company.

MEMORANDUM Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024

Page 3

Many of the comments received during the public hearing expressed similar concerns. These comments have been combined, where possible, and edited for clarity and brevity. Verbatim statements can be found in the *Noramco Inc. Application for Natural Minor Construction Permit November 7, 2023,* Hearing Transcript prepared by VeriText Legal Solutions.

General Public Comment Summary	AQ Responses
 GEORGE X., PENNY DRYDEN, DONNA HITCHNER, JOSEPH WALLS, DAVON HALL: (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 10/26/23, 10/31/23, 11/07/23) Concerns related to public health impacts and baseline community health risks. 	The emissions from the proposed project were modeled in AERSCREEN, a dispersion modeling tool, in order to determine the Maximum Downwind Concentration (MDC) of each pollutant. The modeling results were compared to established health-based safety screening levels. A safety factor of 100 is applied to the screening level in order to meet AQ's criteria. This accounts for health impacts on vulnerable members of the population.
	Emissions for each pollutant that will be emitted as part of this process were below AQ's screening criteria, and therefore, are not presumed to negatively impact human health, welfare, or the environment.
	During the community information session, the Department presented results from the Environmental Protection Agency's (EPA's) Air Toxics Screening Assessments (AirToxScreen). The 2019 AirToxScreen cancer and noncancer risk data for the area the facility is located in shows that the risk is considered low (30 in 1,000,000) and is below EPA's upper limit of acceptable risk (1 in 10,000).
 GEORGE X., PENNY DRYDEN: (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 10/26/23, 10/31/23, 11/07/23) Concerns related to the relationship between hazardous air pollutant (HAP) emissions and Covid-19. 	HAP emission limits in air permits are developed from Federal and State regulatory requirements and the health-based safety screening levels that are discussed above.
	Federal and State regulatory requirements are based upon a regulatory development process supported by scientific data. The regulatory

Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 4

General Public Comment Summary AQ Responses development process is lengthy and can take many years. At this time there have been no changes to Federal or State regulations for HAPs based upon the Covid-19 pandemic. The emissions from the proposed project meet all Federal and State regulatory requirements and AQ's health-based screening criteria. AQ reviews permit applications to ensure that the proposed process, **DONALD FARRELL:** (VERBAL COMMENTS DATED 11/07/23) Concerns related to the type of product being equipment, and emissions meet Federal and State Air regulatory • requirements. The Department does not have the authority to control the produced at Noramco. type of product a facility produces. Noramco submitted a confidentiality request with the application on **DONALD FARRELL:** (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 11/22/23) August 17, 2023, requesting that certain information disclosed in the Concerns related to confidentiality. application be entitled to confidential treatment and an affidavit that substantiates their claim of confidentiality. The request was submitted in accordance with the requirements of 8 DE Admin. Code 900, Section 6, the Department of Natural Resources and Environmental Control's Policies and Procedures Regarding FOIA Requests (FOIA Policy). Section 6.1 of the regulation states: "A person may request that certain records or portions of records submitted to DNREC be held confidential. Certain information may be determined confidential if its disclosure could potentially cause substantial competitive harm to the person or business from whom the information was obtained. The following section sets forth procedures and criteria by which DNREC will determine confidentiality of records or portions of records,"

Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 5

General Public Comment Summary	AQ Responses
	The information requested to be held confidential primarily pertains to the name of the product, batch quantities, raw materials, and intermediates used that have no emissions associated with them, and the chemical manufacturing process itself, as Noramco considers the details of this information to be trade secrets. Noramco holds patents for the development of this process and would suffer significant loss if this information were revealed to Noramco's competitors.
	In accordance with Section 6.2 of this regulation, Noramco's confidentiality request outlined the measures taken to protect against undesired disclosure of information to others, the extent to which confidential information is disclosed, and the precautions taken to ensure secrecy of any disclosed information. The request also attested in the notarized affidavit that considerable time and effort had been invested in the development of this proprietary process and the substantial harm that would result from this information being disclosed to Noramco's competitors.
	During the information session, concerns were raised regarding certain redactions made in the application and a concern that emissions may be held confidential. AQ does not afford confidentiality to emission data. Emissions from this application request are shown in the application and in the public notice. Any redacted materials used in the process are raw materials or intermediates that have no emissions associated with them.
 DONALD FARRELL, DONNA HITCHNER: (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 11/22/23) Concerns related to emergency response planning and equipment failure. 	All equipment covered by an Air Permit must be operated in a manner consistent with good air pollution control practices for minimizing emissions. This includes maintaining the equipment as required for safety.

Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 6

General Public Comment Summary	AQ Responses
	As a Title V facility, Noramco is required to report any discharge in excess of any permit limits to the Department's 24-hour Environmental Emergency Notification and Complaint line, in accordance with Condition 3(c)(2) of Permit: <u>AQM-003/00324 (Renewal 1) (Revision 2)</u> . In addition to the emergency notification requirements outlined in the Title V air permit, Noramco is subject to Tier II Emergency Planning and Community Right-To-Know requirements, as well as the regulations governing hazardous waste.
 GEORGE X., WILLIE SCOTT, JOSEPH WALLS, DAVON HALL: (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 11/07/23) Concerns related to communication with the public and community engagement. 	In accordance with 7 DE Admin. Code 1102, a public notice was issued on August 20 th , 2023, in the <u>News Journal</u> and the <u>Delaware State</u> <u>News</u> for 15 days. In response to the public hearing request, AQ also elected to schedule a Community Information Session to better engage with the community and respond to questions and concerns directly. During the information session, members of the community proposed that Noramco take steps to better engage with the community and communicate permitting activity with stakeholders. The proposed permit has been amended to include the following conditions that will ensure that Noramco engages in meaningful communication with the public: "3.19 The facility shall form a "Community Advisory Board" that engages with and communicates regularly with key stakeholders and members of the community."

Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 7

General Public Comment Summary AQ Responses And, "5.5 The facility shall maintain records demonstrating compliance with Condition 3.19. These records may include, but are not limited to: records demonstrating regular meetings with community stakeholders, such as meeting attendance sheets or meeting minutes; records demonstrating communications distributed to the public; any other records that demonstrate compliance with this requirement." WILLIE SCOTT: (VERBAL COMMENTS DATED 11/07/23) The nature of the batched manufacturing process at the facility means Concerns related to carbon monoxide (CO) that the overall emissions are limited by the total number of batches emissions, carbon dioxide (CO₂) emissions, and the produced for all manufacturing lines throughout the facility. Permitted emission limits are typically calculated based on maximizing the total potential to increase emissions overall. number of batches possible in a year (i.e., the number of operating days in a year divided by the total process run time). In practice, the total number of batches produced will be limited by several factors. Many processes use the same equipment and cannot run simultaneously to other processes. Other production rates are dependent on external factors such as quotas and demand. Noramco is not requesting an increase to Facility-Wide permitted Volatile Organic Compound (VOC), HAP, or CO emissions as a result of the requested permit application. The facility's annual emission inventory, which is a requirement for Title V facilities, shows that actual emissions are consistently below permitted emission limits. CO emissions in 2022 were 2.25 tons. VOC and HAP emissions in 2022 were 1.06 and 1.22 tons, respectively.

Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 8

General Public Comment Summary	AQ Responses
 GEORGE X., PENNY DRYDEN, DONNA HITCHNER, JOSEPH WALLS, DAVON HALL: (VERBAL COMMENTS DATED 11/07/23, WRITTEN COMMENTS DATED 10/26/23, 10/31/23, 11/07/23) Concerns related to footprint expansions, land use/zoning, and pharmaceutical manufacturing. 	Both Noramco and AQ emphasized during the information session and during the hearing that the facility is not requesting any land use or zoning modification as part of this permit. Noramco is not requesting an expansion to the plant's footprint. All modifications related to the installation of the new vacuum pump will be within the plant's current footprint. Local zoning and land use determinations do not fall under the authority of DNREC or AQ. In addition, the facility provided information during the public hearing regarding the numerous agencies that inspect the facility on a regular basis, including the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA).

MEMORANDUM Technical Response Memorandum for Noramco, Inc. Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u> Permit Application to Install a Vacuum Pump and Manufacture D8 and D9 January 3, 2024 Page 9

RECOMMENDATIONS

The application was reviewed and determined to be administratively and technically complete in accordance with all relevant regulations. The proposed permit was drafted in accordance with applicable state and federal regulations and was determined to be protective of human health, welfare, and the environment. The Division of Air Quality recommends the issuance of "Draft" Permit: <u>APC-2023/0086-CONSTRUCTION (VOC RACT)</u>.

ADM:ASM:NTA F:\EngAndCompliance\NTA\NTA23081

pc: Dover File