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Produced by the Southeast Regional Office 2025

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fact sheet

Moderna Therapeutics, Inc. • 1 Moderna Way Norwood Non-Major Comprehensive Plan Application No. 24-AQ02P-0005-APP

Introduction

The Massachusetts Department of Environmental Protection ("MassDEP") regulates air pollution emissions from various sources, such as industrial facilities, power plants, and other operations, through the issuance of permits and approvals. These permits outline specific limits and requirements for emissions of certain pollutants. The purpose of these permits is to ensure facilities operate in compliance with state and federal air quality regulations designed to protect public health and the environment. MassDEP evaluates permit applications, sets emission limits based on factors like air quality standards and technological feasibility, and may require facilities to implement pollution control measures or monitoring systems. Facilities must apply for and obtain an air permit or approval before constructing or modifying operations that could potentially emit air pollutants. Compliance with the conditions outlined in the permit is essential to protect human health and for the operator to avoid enforcement actions and potential penalties from MassDEP. Regular inspections as well as testing and monitoring may also be conducted to verify compliance with requirements.

Moderna Therapeutics, Inc. has filed an Air Quality ("AQ") Non-Major Comprehensive Plan Application ("NMCPA") No. 24-AQ02P-0005-APP ("application") with MassDEP for the operation of an existing pharmaceutical production facility at 1 Moderna Way, Norwood, Massachusetts ("Facility").

The proposed operation of the Facility is subject to the Massachusetts Air Pollution Control Regulations (310 CMR 7.00). Prior to commencing construction, the Facility operator is required to apply for and obtain a permit, known as an "Approval." Currently, MassDEP is in the process of reviewing the application. Upon completion of the review, MassDEP will issue a proposed decision, either approving or denying the application. Subsequently, a 30-day public comment period will be provided on the proposed decision. Information regarding how to review the application, receive notification of MassDEP's proposed decision, and submit comments can be found in the "How to Comment" section of this Fact Sheet.

Facility Information

Moderna Therapeutics, Inc. (the "Permittee") operates a pharmaceutical production Facility for the research, development and manufacture of messenger ribonucleic acid ("RNA") drugs for clinical and commercial use. The facility campus is made up of three primary buildings – Buildings #100, 200 and 400, all used for pharmaceutical production purposes. The campus contains multiple additional auxiliary buildings used mostly as office space.

The Permittee began operations at Building #100 in 2018. The building was previously a Polaroid Corporation facility. Operations began at Building #200 in 2020. The building was previously a Universal Technical Institute educational campus. Operations began at Building #400 in 2021. The building was previously a Mercer, LLC facility.

Prior to March 2021, the Permittee operated the facility under 310 CMR 7.03 Plan Approval Exemption: Construction Requirements, more specifically 310 CMR 7.03(25): Biotechnology Surface Disinfection Processes. This exemption limits total facility-wide actual emissions to 15 tons of volatile organic compounds ("VOCs") per consecutive 12-month period and 2.5 tons of VOCs per calendar month. The exemption additionally limits single Hazardous Air Pollutant ("HAP") emissions to less than nine tons per consecutive 12-month period and 2 tons per calendar month, and limits combined HAP emissions to less than 15 tons per consecutive 12-month period and 3 tons per calendar month.

In March 2021, MassDEP conducted an onsite compliance inspection of the Facility and determined that the Permittee exceeded the Plan Approval exemption limits of 310 CMR 7.03(25) and failed to obtain an Air Quality Plan Approval from MassDEP pursuant to 310 CMR 7.02(5)(a)1. The compliance inspection identified that actual VOC emissions at the Facility exceeded 15 tons during consecutive 12-month periods since February 2021, continuing to the present time.

Based on the inspection conducted and additional information received, MassDEP's Southeast Regional Office ("SERO"), Bureau of Air & Waste ("BAW") Compliance and Enforcement Section entered into an Administrative Consent Order with Penalty ("ACOP") in December 2023 for violating the Comprehensive Plan Application requirement of 310 CMR 7.02(5)(a)1. The ACOP required the Permittee to submit the appropriate AQ Plan Application in accordance with 310 CMR 7.02.

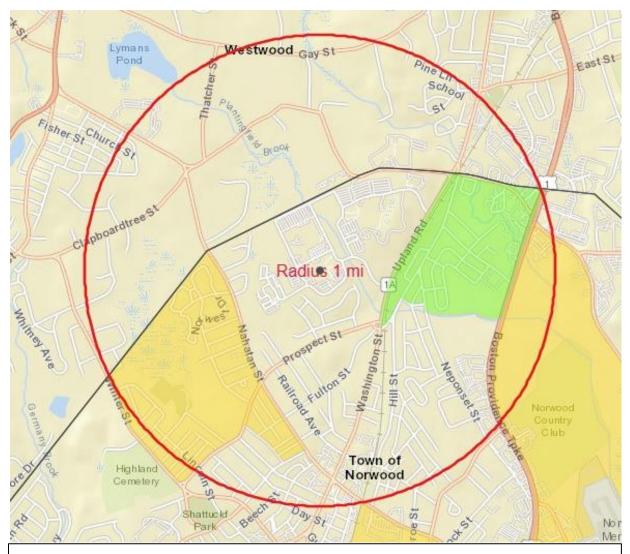
Additionally, on September 14, 2024, the Permittee submitted an AQ Restricted Emissions Status ("RES") Application to restrict potential nitrogen oxide emissions from fuel-burning equipment at the Facility to less than 49 tons per consecutive 12-month period. An RES Approval was issued for the Facility on January 24, 2025, after review of the application by MassDEP's SERO, BAW Air Permitting Section and a public comment period, during which no comments were received.

Environmental Justice

Environmental Justice ("EJ") centers around the belief that everyone deserves protection from pollution and the opportunity to thrive in a clean, healthy environment. It embodies the idea of fair treatment and meaningful participation for all individuals regarding the creation, execution, and enforcement of environmental regulations, as well as the fair allocation of environmental advantages. MassDEP employs United States ("US") census data to pinpoint census block groups designated as environmental justice areas, using criteria such as income, minority population percentage, and language accessibility. MassDEP is dedicated to ensuring that inhabitants of EJ areas have the opportunity for meaningful engagement in MassDEP activities within their community. For more information on MassDEP's EJ program please visit https://www.mass.gov/environmental-justice or you can also contact Debbie Marshall-Hewlitt, MassDEP's Southeast Regional Office Environmental Justice Coordinator at Deborah.marshall-hewlitt@mass.gov, (774) 384-3564.

MassDEP is required to identify if there is an EJ designated population within a one-mile radius of facilities submitting a Non-Major Comprehensive Plan Application. Within the applicable one-mile radius of the Facility, the following EJ designated areas have been identified: Block Group 1, Census Tract 4133 by the criteria Minority; Block Group 7, Census Tract 4131 by the criteria Minority; and Block Group 1, Census Tract 4132.01 by the criteria Income. The one-mile radius does extend into the town of Westwood; however, the radius does not include EJ areas in that community. This data was obtained from the EEA EJ Map Viewer Tool at https://www.mass.gov/info-details/massgis-data-2020-us-census-environmental-justice-populations.

Within one mile of the facility there are identified census tracts where at least 5% of the population has Portuguese and Spanish speakers in the homes of public school students, who reported they speak a language other than English. Accordingly, this EJ Fact Sheet and forthcoming Notice of Public Comment period will be translated into Portuguese and Spanish and circulated within the community.



Minority: the block group minority population is \geq = 40%, or the block group minority population is \geq = 25% and the median household income of the municipality the block group is in is < 150% of the Massachusetts median household income



Income: at least 25% of households have a median household income 65% or less than the state median household income

Project Information

VOCs and HAPs are emitted from the Facility during multiple operations associated with pharmaceutical production processes. The majority of VOC emissions are generated from the surface disinfection and other miscellaneous chemical usage and handling in the Facility laboratories. HAPs are also emitted from surface disinfection and miscellaneous chemical usage and handling.

Additional VOC emissions are emitted from the pharmaceutical production processes, the preparation of solutions for pharmaceutical production, and from the Facility wastewater transfer system.

All VOC and HAP emissions from pharmaceutical production processes are exhausted untreated through Facility ventilation to the atmosphere. The Permittee has proposed short-term and long-term operational and emission limitations on each process that generates VOC and HAP emissions. The Permittee has additionally proposed best management practices for surface disinfection, such as the proper handling and storage of volatile solvents.

With the proposed operational restrictions, the Facility's maximum potential emissions of VOCs and HAPs from pharmaceutical production processes will be approximately 47.06 tons of VOCs per consecutive 12-month period and 6.64 tons of HAPs per consecutive 12-month period. These emissions will be in addition to emissions of nitrogen oxides ("NOx"), carbon monoxide ("CO"), sulfur dioxide ("SO2"), particulate matter ("PM"), VOC and HAP emitted from the Facility's fuel burning equipment. Please see the following table for illustration purposes:

Facility Potential Emissions (Tons per consecutive 12-month period)						
	NO _x	СО	SO ₂	PM	VOC	HAP (Combined)
Facility Pharmaceutical Production Processes Potential to Emit					47.06	6.64
Facility Fuel-Burning Equipment Potential to Emit	49.26	28.48	0.02	3.53	2.92	4.37
Total Facility Potential to Emit	49.26	28.48	0.02	3.53	49.98	11.01

How to Comment

MassDEP is currently reviewing the NMCPA No. 24-AQ02P-0005-APP. The application is currently available for public review via the EEA ePLACE Public Access Portal: https://eeaonline.eea.state.ma.us/EEA/PublicApp/

On the main Executive Office of Energy and Environmental Affairs ("EEA") ePLACE Portal page, click on the orange "Search and/or Comment" button, then on the name of the applicant/facility on the resulting page.

After MassDEP completes its review of the application, MassDEP will issue a proposed decision, subject to a 30-day public comment period. This information will also be posted in the ePLACE Public Access Portal.

Contact Information

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