



Board of Supervisors Memorandum

August 10, 2021

Update on Becton, Dickinson and Co. (BD) Ethylene Oxide Sterilization Facility at Kolb and Valencia - Air Quality Permit Status

Background

Attached is an update from Pima County's Department of Environmental Quality (PDEQ) on the status of the BD ethylene oxide sterilization facility's air quality permit request. Per the Board's discussion at the July 6, 2021 meeting, included in this update is the schedule for public hearings, public notification area, impacts of ethylene oxide (EO), EPA concerns and EO issues in other locations. Given the toxic nature of EO, it is important that sufficient public notice be provided to area residents to allow them to participate in this process.

BD Facility and Air Quality Permit

As previously stated in prior updates, BD is seeking an air quality permit for emissions to operate their ethylene oxide sterilization facility to be constructed at Kolb and Valencia. Attachment D of PDEQ's memorandum provides information on EO, a regulated hazardous air pollutant. Ethylene oxide has been in the news due to its highly flammable and toxic nature. The EPA increased the cancer risk value for EO 5 years ago and has found it to be 60 times more carcinogenic to humans than previously thought. The agency has been reassessing the long-term risk of exposure to EO in light of recent studies and findings.

Attachment D also provides additional sources and information links, including the March 2020 opinion of the Office of Inspector General calling for the EPA to notify residents living near high EO emitting facilities about the increased cancer risks.

As indicated by PDEQ, BD will be required to control 99 percent of its air emissions of EO and subject to strict testing and reporting requirements.

Permit Schedule and Public Notification

The permit process schedule is still on track, with the proposed draft permit being made available later this month. The draft permit and other pertinent information will continue to be made available to the public on PDEQ's link BD & Company Ethylene Oxide Sterilization Facility. Two open houses and public hearing will be held during September and October (proposed locations provided in the attached update), with the public review and comment period closing in November. A 30-day public review period is usually planned, but given the nature of the pollutant and the area, PDEQ will issue a 90-day review period. The EPA has agreed to review the permit concurrently during the public notice period. The final permit is projected to be issued in January 2022.

As part of the permit process, PDEQ also conducted an Environmental Justice Analysis for this area to determine the demographic and environmental indicators that should be considered when identifying the impact area. A 1-mile radius is the minimum recommended area. However, population demographics vary widely within this area, which encompasses

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JUL 05 21 PM 04 15 PCC CLK B

The Honorable Chair and Members, Pima County Board of Supervisors

Re: **Update on Becton, Dickinson and Co. (BD) Ethylene Oxide Sterilization Facility at Kolb and Valencia - Air Quality Permit Status**

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Littleton to Vail, and PDEQ will use a 3-mile notification radius as shown on page 2 of their update.

Additional Comments

At the July 6th meeting, the Board also inquired about concerns expressed by Davis-Monthan Air Force Base (DM). We understand DM expressed concerns early to BD and the City of Tucson when locations were being discussed near the base and their approach/departure flight corridor (ADC). Both the County and City zoning codes prohibit the storage of any hazardous or flammable substances within the ADC. The BD facility's chosen location is at the corner of Kolb and Valencia, adjacent to the base and in proximity to the ADC (Attachment B of the update). The parcel is located within the City limits. It should be noted that DM's concerns do not fall within PDEQ scope of review, since their comments fall outside of their air quality purview.

As we understand it, DM is concerned about the large amount of EO projected to be stored onsite, given its flammability and location. Additionally, it was noted that BD has facilities in other states, but none have been built within close proximity to an airport, much less an air force military installation and associated flight paths. DM was also concerned that the design and modeling provided to them by BD does not account for possible catastrophic accident response given its location and toxicity of EO and impact to the surrounding areas. DM conveyed their support of the business, but at a location where this sized EO facility is not in close proximity to businesses, neighborhoods and military base.

Recommendation

I recommend the Board approve the PDEQ proposed public notification and schedule for the air quality permit review process for BD.

Sincerely,



C.H. Huckelberry
County Administrator

CHH/anc – August 5, 2021

Attachment

c: Jan Leshner, Chief Deputy County Administrator
Carmine DeBonis, Jr., Deputy County Administrator for Public Works
Ursula Nelson, Director, Pima County Environmental Quality
Diana Durazo, Special Projects Manager, Pima County Administrator's Office



MEMORANDUM

DATE: July 30, 2021

TO: C. H. Huckelberry
County Administrator

FROM: Ursula K. Nelson, P.E. *UKN*
Director

RE: Update on Becton, Dickinson and Company (BD) Air Quality Permit

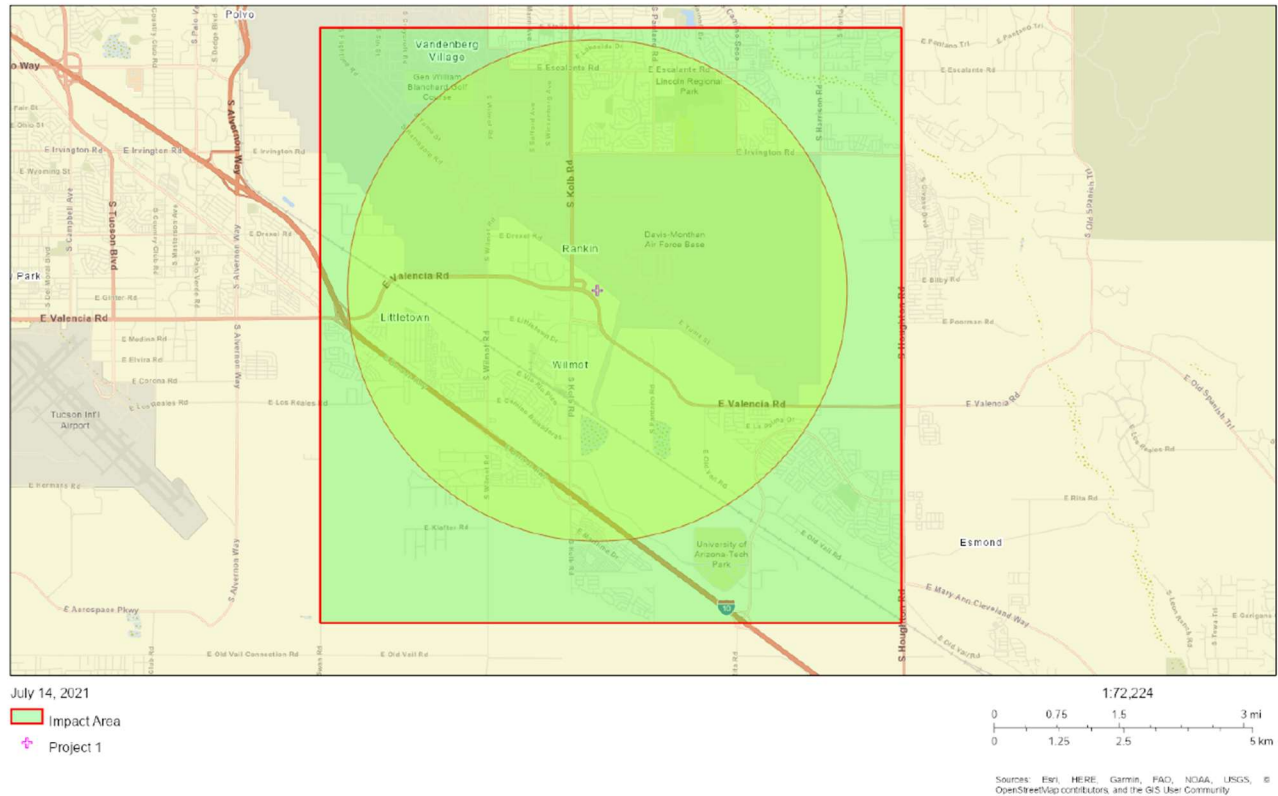
On April 13 the Pima County Department of Environmental Quality (PDEQ) provided information to your office that BD has applied for an air quality permit for a new ethylene oxide (EO) commercial sterilization facility in Tucson. A subsequent memorandum regarding BD was sent from your office to members of the Board of Supervisors on May 26 (Attachment A). The proposed facility will be built at the northeast corner of Valencia and Kolb Road in the City of Tucson (Attachment B). On June 17 PDEQ provided a projected permit issuance schedule for the air quality permit (Attachment C).

As mentioned in the June update, EO is a highly toxic and flammable gas and the U.S. EPA has identified EO as carcinogenic to humans, increasing the risk of cancer. Attached is additional information on EO, EPA involvement and concerns around it and issues elsewhere (Attachment D).

As specified in the federal rules regulating these facilities, BD will be required to control 99% of the facility's air emissions of EO through the operation of air pollution control devices. Although PDEQ is not allowed to be more stringent than EPA in the required level of air emissions controls, the source will be subject to stringent testing and reporting requirements to ensure compliance. The City has designated this area as one zoned to allow this type of operation.

PDEQ conducted an Environmental Justice (EJ) Analysis for this location utilizing the tool recommended by the EPA *EJ Screen*. For this analysis, an "impact area" needed to be designated in order to assess the environmental and demographic indicators that should be considered to estimate the impacts of siting this vicinity in this particular location. A 3-mile radius from the proposed site location was selected in order to ensure that all of the surrounding communities would be included for this analysis, as well as for the public outreach (a 1-mile radius is the minimum recommended impact area per *EJ Screen*). Highly variable demographics exist within this impact area, with very low income and minority populations to the southwest (Littleton) and north, and more affluent populations to the southeast (Vail). The identified impact area for purposes of this EJ Analysis encompasses approximately 50 square miles and includes a population of 50,369. PDEQ believes it is important to include all of these nearby communities in our public outreach for the permitting process. In order to ensure that adequate public outreach is achieved prior to the issuance of this air quality permit, we have decided to host two open houses in different locations (tentatively planned at

Lauffer Middle School on E. Littletown Road and Santa Rita High School on S. Pantano Road near E. Escalante Road), one virtual open house, and one public hearing, also at Lauffer. Notification of these public meetings will be written in English and Spanish and sent to all of the addresses within the impact area. Spanish translators will also be available at each of the meetings. The opportunity for public review will be available for 90 days (extended from the required minimum of 30 days), ensuring plenty of time for the public to provide comment.



We are available to discuss this further at your convenience.

UKN/sr

c: Carmine DeBonis Jr., Deputy County Administrator for Public Works

ATTACHMENT A



MEMORANDUM

Date: May 26, 2021

To: The Honorable Chair and Members
Pima County Board of Supervisors

From: C.H. Huckelberry
County Administrator

A handwritten signature in dark ink, appearing to be "CH", is written over the printed name "C.H. Huckelberry".

Re: **Information on the Becton, Dickinson and Company sterilization facility's application for an air quality permit**

In early April, it was announced that Becton, Dickinson and Company (BD) will construct a 120,000 square foot facility on 32 acres at the northeast corner of Kolb and Valencia, adjacent to the southern boundary of Davis-Monthan Air Force Base (DMAFB) and in proximity to their Approach/Departure Corridor (Attachment 1). The facility is an ethylene oxide sterilization plant for medical equipment and will be operational in mid-2022, with an approximate hire of 40 new jobs. The project development approvals are being processed by the City of Tucson.

Due to the facility's emissions, BD is required to apply for an air quality permit from the Pima County Department of Environmental Quality (PDEQ). Attached is a memorandum from Ursula Nelson on BD's air quality permit application and process (Attachment 2). Of primary concern is BD's possible emission of ethylene oxide (EO). EO is a highly toxic and flammable gas used as a sterilizing agent for medical equipment. The U.S. Environmental Protection Agency (EPA) identified EO as carcinogenic to humans, increasing the risks of cancer, and is currently reviewing ethylene oxide regulations for possible changes to the rules to impose stricter emissions standards based on results of the latest National Air Toxics Assessment. PDEQ is working with the EPA to ensure the current rules are being complied with by the company, and to the extent possible, give consideration to the discussion on new rules by the EPA.

PDEQ anticipates an extensive and active public participation process. The permitting process will include public meetings, a 90-day public review period and public hearing. As noted in the memorandum, PDEQ has also established a webpage for the public to be able to access communications and information on BD's permit application and materials for review (Attachment 3). Information will continue to be provided to the Board throughout this process.

c: Jan Leshner, Chief Deputy County Administrator
Carmine DeBonis Jr. Deputy County Administrator for Public Works
Ursula Nelson, Director Department of Environmental Quality
Diana Durazo, Special Projects Manager, County Administrator's Office

ATTACHMENT 1

BD (Becton Dickinson Company) Facility Site

0 1,000 ft



cmo1371

**Davis-Monthan
Air Force Base**

Valencia Rd

**Subject Parcel
32.7 acres**

Kolb Rd

amazon

**Port of
Tucson**

**Port of
Tucson**

Valencia Rd

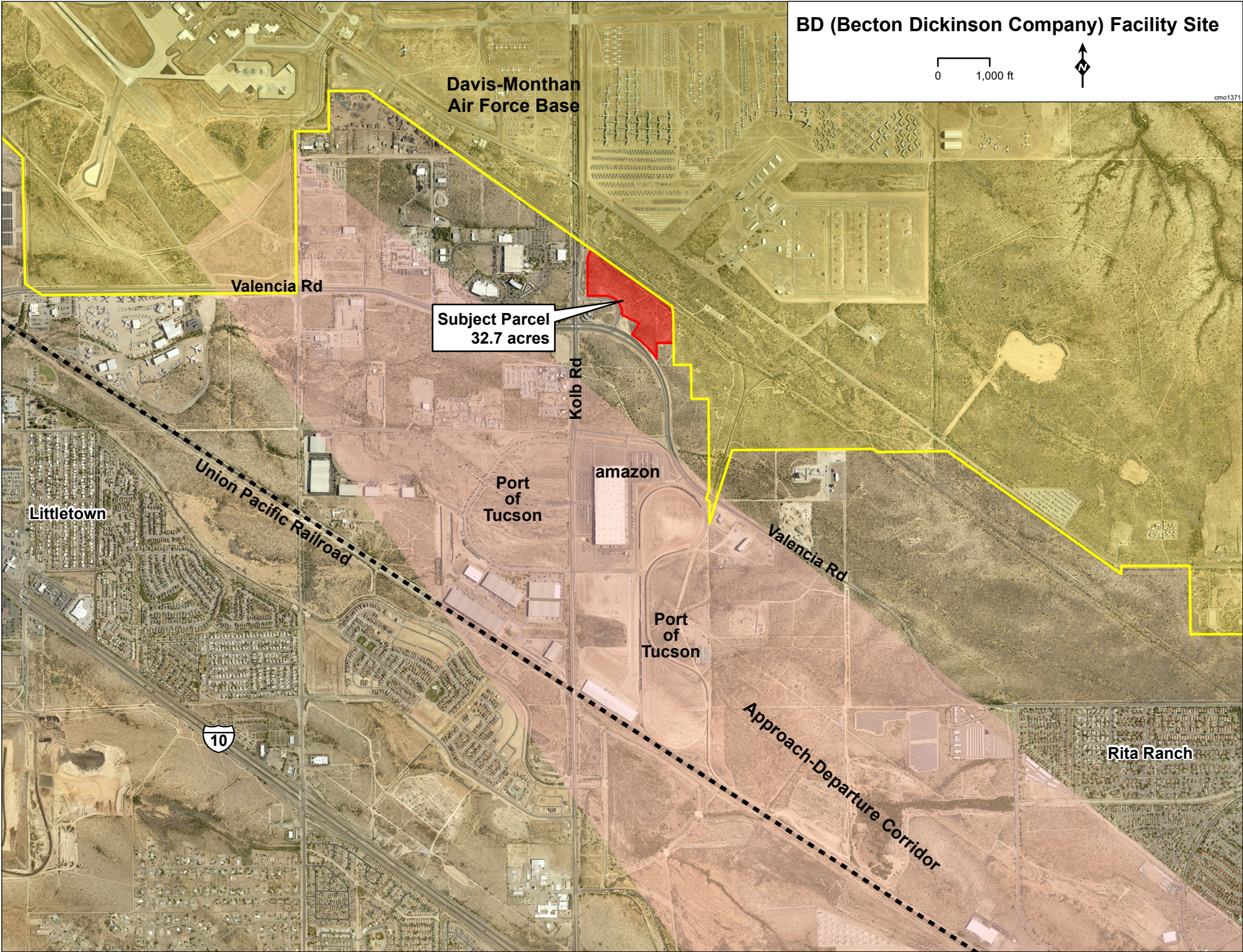
Union Pacific Railroad

Littletown

10

Approach-Departure Corridor

Rita Ranch



ATTACHMENT 2



MEMORANDUM

DATE: April 13, 2021

TO: C.H. Huckelberry
County Administrator

FROM: Ursula K. Nelson, P.E.
Director

UKN

RE: Becton, Dickinson and Company (BD) Ethylene Oxide Sterilization Facility Air Quality Permit Application

Pima County Department of Environmental Quality (PDEQ) has received an air quality permit application from Becton, Dickinson and Company (BD) for a new ethylene oxide commercial sterilization facility in Tucson. The proposed facility will be built at the northeast corner of Valencia and Kolb Road within the City of Tucson. Its purpose will be to sterilize medical products such as surgical kits, intravenous (IV) catheters and sets, surgical and vascular devices and various types of syringes.

The primary pollutant of concern from the BD facility is the emissions of Ethylene Oxide (EO) from the sterilization process. EO is regulated as a Hazardous Air Pollutant and is carcinogenic through inhalation. The facility will be required to control 99% of EO emission through the operation of air pollution control devices.

PDEQ has established a webpage with relevant information for this facility which can be found at:

[BD & Company Ethylene Oxide Sterilization Facility](#)

PDEQ will also be conducting public meetings and a public hearing on any proposed air quality permit. A 90-day public comment will be provided for this proposed permitting action.

If you would like additional information, please contact me at 724-7454 or Richard Grimaldi, Deputy Director, at 724-7363.

UKN/sr

cc: Carmine DeBonis Jr., Deputy County Administrator for Public Works
Richard Grimaldi, PDEQ Deputy Director



Figure 2-1. Site Location

ATTACHMENT 3

BD & Company Ethylene Oxide Sterilization Facility

Pima County Department of Environmental Quality (PDEQ) has received an air quality permit application from Becton, Dickinson and Company (BD) for a new ethylene oxide sterilization facility in Tucson.

The proposed facility will be constructed on a 32.7-acre parcel (Block 1 - labeled in map) in the Century Park Marketplace. Its purpose will be to sterilize various medical products such as surgical kits, intravenous (IV) catheters and sets, surgical and vascular prep devices and various types of syringes.






The air quality permit application is being reviewed under the Clean Air Act, Federal and State requirements. The BD facility will also be subject to local Environmental, Health and Safety Requirements. Since PDEQ is operating under a delegation agreement from EPA for this type of facility, EPA will be consulted and involved in the whole process including review of any public comments.

WEBPAGE UPDATED ON A REGULAR BASIS AS DOCUMENTS BECOME AVAILABLE

The information below provides a chronological list of the documentation related to the air quality permit process from the projects inception to its conclusion. PDEQ is utilizing this repository webpage to provide easy access to the documents for the public comment period and to facilitate an open dialogue and the sharing of information with all interested parties.

Permit Application Documentation

Date Received	Document Title
04-08-2021	Permit Application 
04-06-2021	Application Complete and Request for Additional Information 
05-03-2021	BD Response to additional information dated 04-06-2021 

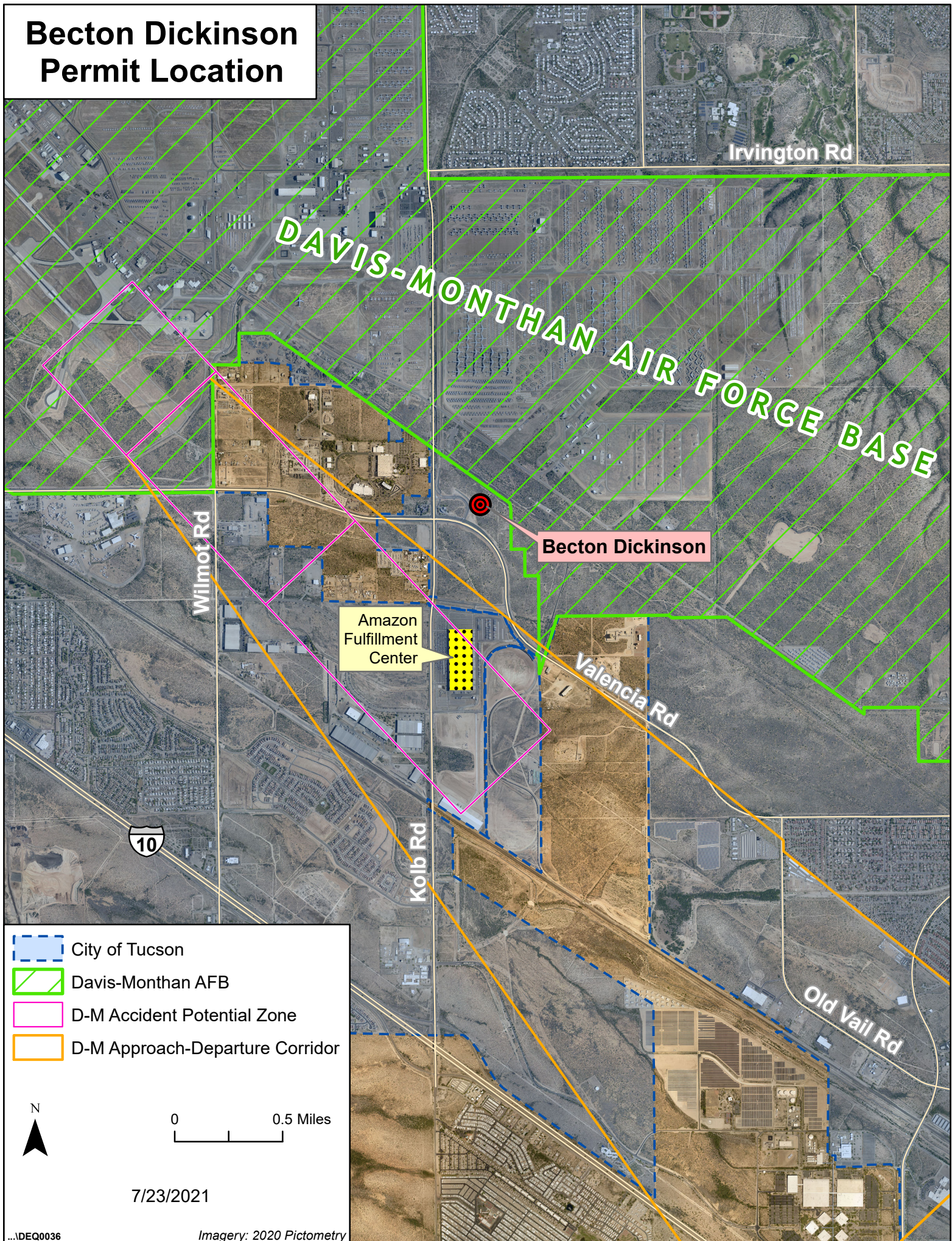
Permit Compliance & Testing Documentation

Date Received	Document Title



ATTACHMENT B

Becton Dickinson Permit Location




ATTACHMENT C



MEMORANDUM

Date: June 17, 2021

To: The Honorable Chair and Members
Pima County Board of Supervisors

From: C.H. Huckelberry 
County Administrator

Re: **Update on Becton, Dickinson and Company (BD) Air Quality Permit Application and Projected Permit Issuance Schedule**

In my memorandum dated May 26th, I informed the Board of BD's application to the Pima County Department of Environmental Quality (PDEQ) for an air quality permit for their new medical equipment sterilization facility using ethylene oxide, located at Kolb and Valencia adjacent to Davis-Monthan Air Force Base.

As stated previously, the development permitting is being processed by the City of Tucson. Comments from Davis-Monthan Air Force Base have been submitted to the City expressing significant concerns over the BD facility. We invite the public and those who have provided information, to submit comments to PDEQ as this project proceeds through the process.

Attached is PDEQ's projected schedule for BD's air quality permit process (Attachment 1), with permit available for public review estimated in August. Given the nature of ethylene oxide and its location, multiple open houses will be held for public input. All current information on this air quality permit can be found at PDEQ's website at [BD & Company Ethylene Oxide Sterilization Facility](#). Updates will continue to be provided to the Board.

Attachment

c: Jan Leshner, Chief Deputy County Administrator
Carmine DeBonis Jr. Deputy County Administrator for Public Works
Ursula Nelson, Director Department of Environmental Quality
Diana Durazo, Special Projects Manager, County Administrator's Office

ATTACHMENT 1



Air Quality Permit Processing Proposed Schedule Becton Dickinson and Company (BD)

Pima County Department of Environmental Quality (PDEQ) has received an air quality permit application from Becton, Dickinson and Company (BD) for a new ethylene oxide sterilization facility in Tucson. The proposed facility will be constructed on a 32.7-acre parcel in the Century Park Marketplace. Its purpose will be to sterilize various medical products such as surgical kits, intravenous (IV) catheters and sets, surgical and vascular prep devices and various types of syringes.

The PDEQ Air Program has developed the following draft schedule for the permit process.

- April, 2021 Application Received
- June, 2021 Preliminary Draft Permit Available for BD Review
- August, 2021 Proposed Permit Available for Public Review
- September, 2021 1st Public Open House
- September, 2021 2nd Public Open House
- October, 2021 Public Hearing
- November, 2021 End of Public Review
- December, 2021 Draft Response to Public Comments
- January, 2022 Notice of Intent to Issue Final Permit
- January, 2022 Issue Final BD Air Permit
- January, 2022 30-day Appeal Window (Pima County Hearing Board)

Note: The schedule is based on the following:

There are no significant technical issues with the permit application.

There will be no significant public comments that will require re-public notice of the permit.

EPA agrees to concurrent review of the permit during public notice

ATTACHMENT D

EO Background

EO is a vital raw material used in large-scale chemical production with many diverse applications. 90%-95% of EO production is in the use as a raw feedstock in the manufacture of glycols, polymers, and various consumer and non-consumer organic chemicals, compounds, and their intermediates, to include detergents, thickeners, solvents, and plastics. Its primary use is for the synthesis of ethylene glycols, including diethylene glycol and triethylene glycol, which accounts for up to 75% of global EO consumption.

Since 1938 EO has also been used as a sterilant/fumigant. For many decades EO has been used commercially in the production of medical equipment supplies and other miscellaneous sterilization/fumigation operations. EO's use as a sterilant/fumigant makes up about 5%-10% of global consumption. EO has an "non-ideal" bond angle with oxygen that gives the gas molecule a significant molecular angular strain. This atomic strain makes EO gas molecule unstable and highly reactive. It has the ability to react with many nucleophiles and open the C = C double bond ring of many organic compounds. Through these alkylation, addition, or substitution, type reactions, EO can readily react with microorganisms at the cellular nuclear level. Its reactivity to cellular surfaces, makes EO is a very effective cytotoxic agent that can break down and cross cellular membranes. This reactive property of EO is exploited in modern commercial sterilization and fumigation operations to sanitize and/or sterilize medical instruments and supplies that may be otherwise too sensitive or incompatible to sterilize by using, heat, steam or other techniques.

EO is a suspected carcinogen and identified as a mutagenic, and teratogenic chemical. The EPA identified EO as a hazardous air pollutant (HAP) in §112(b) of the CAA and pursuant to §112(d) the CAA on December 6, 1994, promulgated the National Emission Standard for Hazardous Air Pollutant (NESHAP), Subpart O standards for the ethylene oxide commercial sterilization and fumigation operation(s) source category to protect the public health and welfare from potential emissions from this industrial source category. As provided in Title 17, Pima County DEQ was granted formal authority to administer Subpart O effective August 27th, 1999 by the Director of EPA Region 9 [64 Fed Reg. 34561 (June 28, 1999)].

As part of the permit application, BD has proposed additional limitations that exceed the current Subpart O requirements and are designed to provide an extra margin of safety to protect the health and welfare of the public in the surrounding areas from potential EO inhalation exposure.

Currently, the EPA is reviewing the implementation of the Subpart O source category rule. As part of its mandate, EPA is required to perform a Risk and Technology Review (RTR) to assess any residual risk to the public health and welfare from the NESHAP standards within the first 8 years of promulgating the standards, and are only required to conduct a technology review every eight years after conducting the RTR, to account for any improvements in air pollution controls for the industry. The EPA's integrated risk information system (IRIS) contains published EO risk and hazard studies published by the EPA of associated risks from chronic prolonged exposure to EO. Since 2018, the EPA has re-assessed risk from long term exposure to EO in light of recent studies and findings and has determined it to be about 60 times more hazardous that had been previously estimated. EO is a regulated hazardous air pollutant as it is a suspected

carcinogen and identified as a mutagenic, and teratogenic chemical.

In May 2021, the U.S EPA Office of Inspector General (OIG) published a finding¹ that EPA should conduct a new RTR for EO to protect human health. As part of its RTR rule review, the EPA is currently in the process of collecting information for this source category and requesting data from states and local agencies on monitored ambient air concentrations of EO and working to study and determine the design levels necessary for this source category to continue to protect the health and welfare of the public over a lifetime of inhalation exposure.²

Within the last few years, EPA's air toxics program in coordination with state and local agencies has gathered data on the ambient air levels of EO pollutant in various locations around the country. The EPA continues to review monitored EO background ambient air concentrations observed in certain areas of the country that are far removed from any localized sources attributable to EO's measured presence. Monitoring data in some areas of the country show low concentrations of EO measured above the monitoring method detection threshold and above safe levels, while others areas show little or no measurement of the contaminant at below the lower detection threshold of current analytical methods to detect EO in ambient air.

Issues Elsewhere

As mentioned above, EPA has identified significant health risks to the public from ethylene oxide emissions. A March 31, 2020 preliminary report presents the opinion of the OIG calling for EPA to inform residents who live near facilities with significant ethylene oxide emissions about the elevated estimated cancer risks so that they can manage their health risks³.

EPA has also published a website providing latest information and updates on EO:

<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide>

Also a brief question and answers document:

https://www.epa.gov/sites/default/files/2020-09/documents/background_eto_monitoring.september_2020.pdf

¹ <https://www.epa.gov/office-inspector-general/report-epa-should-conduct-new-residual-risk-and-technology-reviews>

² <https://www.federalregister.gov/documents/2021/05/10/2021-09794/information-collection-request-submitted-to-omb-for-review-and-approval-comment-request-ethylene>

³ <https://www.epa.gov/office-inspector-general/report-management-alert-prompt-action-needed-inform-residents-living-near>