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Ortho-Clinical Diagnostics Raritan Borough, NJ

Proposed Corrective Action Permit Modification Public Meeting

Monday, October 6, 2025 5:00 p.m.





Agenda

- Welcome
- Introduction
- Presentations
- Questions and Comments
- Closing

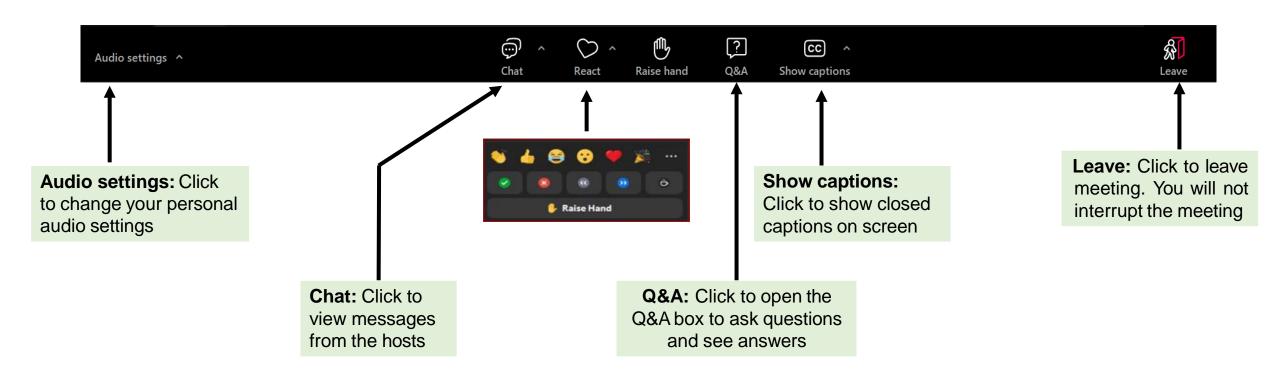


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- Welcome
- Introduction, Steven Petrucelli, EPA
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Zoom Features





This meeting is being recorded to capture key meeting takeaways and comments.

These slides will be added to the EPA's webpage for the site.



Objectives of this Meeting

- Help the community to understand the hazardous waste permit process and site activities — past, present, and future;
- Provide an opportunity to ask questions about the process and cleanup plans; and,
- Inform the public of the opportunity to provide comments to the EPA on its proposed permit modification.

Goal: Ensure that the community remains informed and involved in the EPA's decision-making



Presentations

- Permitting Process and History (EPA)
- Site Background (Ortho)
- Site Investigation and Cleanup (Arcadis)
- Proposed Permit Modification (EPA)
- How to Provide Effective Comments to the EPA (EPA)

EPA and Ortho Speakers



<u>EPA</u>

Andy Park

RCRA Project Manager

Steven Petrucelli

Community Involvement Coordinator

Ortho-Clinical Diagnostics

Tim Goddeyne

Environmental Health & Safety Ortho

Purvee Mittal

Environmental Consultant Arcadis

Darren Scillieri

Environmental Consultant Arcadis

Questions and Comments





- Please hold questions until the end or place them in the Q&A box to be answered later.
- You can add comments in the chat box.



Terminology: RCRA & HSWA



Federal Solid and Hazardous Waste Laws:

Resource Conservation and Recovery Act, also referred to as RCRA

 Hazardous and Solid Waste Amendments, also referred to as **HSWA**



Presentations

- Permitting Process & History, Andy Park, EPA
- Site Background
- Site Investigation and Cleanup
- Proposed Permit Modification
- How to Provide Effective Comments to the EPA

EPA Permit (HSWA Permit) Process



- RCRA Permit Application
- RCRA Permit
 - Hazardous Waste Management Units by NJDEP
 - Cleanup (or Corrective Action) by EPA
 - Others (Waste Minimization, Land Disposal Restrictions, etc) – by EPA

EPA Permit (HSWA Permit) Process



- Hazardous and Solid Waste Amendments (HSWA) Permit
 - Draft HSWA Permit
 - Public Notice
 - Final HSWA Permit

- HSWA Permit Modification
 - Draft HSWA Modification
 - Public Notice
 - Final HSWA Modification

Permit History for the Site



- RCRA Permit (Part B) Application, 1984
- NJDEP's Hazardous Waste Management (HWM) Permit, 1988
 - 4 Units (incinerator, 2 container storage area and one above ground tank) subsequently closed
 - HWM Permit terminated, 1991
- EPA HSWA Permit, 1988



Presentations

- Permitting Process & History
- Site Background, Tim Goddeyne, Ortho
- Site Investigation and Cleanup
- Proposed Permit Modification
- How to Provide Effective Comments to the EPA

QuidelOrtho Environmental, Health and Safety Policy

QuidelOrtho is committed to protecting and improving the health and safety of all individuals. We are also committed to preserving and enhancing the environmental sustainability of our products, global operations, and therefore, our communities, customers, and patients we serve.

We aim to accomplish these commitments by integrating EHS as a pillar of our business operations. We strive for an injury free workplace, and to conserve the earth's resources.

We are committed to regulatory compliance and the continuous improvement of EHS performance, programs, and related management systems. We have established EHS objectives into our business operations and will publicly report our progress to demonstrate our commitment to EHS performance and principles.

Safety is an integral part of our business operations. We hold every employee and representative accountable for following all prescribed safe working practices and procedures. No job or task is so urgent, and no schedule is so rigid that individuals cannot take the time to do their jobs in a safe manner.

All QuidelOrtho employees and representatives are responsible for implementing and applying this EHS policy.

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Raritan Facility Overview



Site Location: Raritan, New Jersey

Site Size
Building Footprint
Building Area
Manufacturing &
Manufacturing &

Warehouse Area

Operations:

• Two shift manufacturing operations, Monday thru Friday

Environmental & Sustainability:

- Solar Power: 1.7Mw Solar Panel Array (10% of Site Energy)
- Co-Generation Turbine System
 - Steam Generation
 - Turbine generates 1.4 megawatts of electrical power

Environmental, Health & Safety Certifications

- ISO14001, 3rd Party Environmental Certification
- OSHA Voluntary Protection Program, Star Site
- New Jersey Department of Environmental Protection; Recognized as an Environmental Stewardship Site

Ortho-Clinical Diagnostics Products Manufactured at Raritan Facility

	Red Blood Cells	Antisera	Donor Screening
Product Purpose	Used with blood typing and antibody screening products.	Traditional reagents used for blood typing/antibody screening.	Designed to test blood donations for exposure of viruses/disease.
Customers	Hospitals, Reference/Private Labs, Donor Centers, Plasma Centers		







Donor Screening



Presentations

- Permitting Process & History
- Site Background
- Site Investigation and Cleanup, Purvee Mittal and Darren Scillieri, Arcadis
- Proposed Permit Modification
- How to Provide Effective Comments to the EPA

Site Overview



Site Facts

EPA ID: NJD068715424

Location: 1001 US Route 202, Raritan, New

Jersey, 08869.

Property Area: 66 acres

Other Names: Ortho Products, Inc.; Ortho Pharmaceutical Corporation; Ortho Products; Ortho Diagnostics Incorporated; Ortho

Diagnostics Systems, Inc.

Cleanup Status: Corrective Action Underway

Human Exposure under Control:

Yes, Controlled

Groundwater under Control:

Yes, Controlled

Last Updated: Sept 2025

"Since the permit was first issued in 1988, Ortho-Clinical Diagnostics [Ortho] has investigated potential releases throughout the site; excavated contaminated soil; decontaminated manholes; cleaned unused process pipelines and sewer lines; and removed various underground storage tanks. The EPA has determined that the company completed cleanup to standards set by the EPA and the [NJDEP], at all but four areas of the site."

Over 35+ years, Ortho has proactively collaborated with EPA and NJDEP to implement successful remedies at each area and will continue their commitment to environmental stewardship with open dialogue with both regulatory agencies.

Permit Background





Facility focuses on research and production operations related to transfusion medicine (donor screening & immunohematology) products.

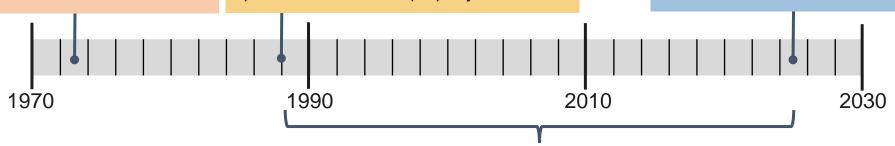
1988: Agencies Issue Environmental Permits

Permits issued by US EPA and NJDEP regulate storage of wastes on property and require facility to investigate releases or spills of wastes on the property.

2025: US EPA Issues Permit Modification

Objective 1: Proposes cleanup activities for 4 areas with residual impacts remaining at the facility

Objective 2: formalizes that areas that have met EPA and NJDEP requirements do not require further action.



1988 to present: Ortho Completes Investigation and Cleanup Activities in Accordance with Permit

- Total of 38 potential areas of environmental impact identified through soil and groundwater investigations
 - US EPA and NJDEP confirmed no further action is necessary at 34 areas
 - 4 areas remaining with residual impacts to be addressed

Summary of Cleanup Activities



34 areas where potential environmental impacts were identified areas and no further action is required

- ✓ 22: no environmental impacts identified (supported by additional data collection and site history review)
- ✓ 12: environmental impacts were successfully investigated and remediated to meet EPA and NJDEP requirements based on sample verification

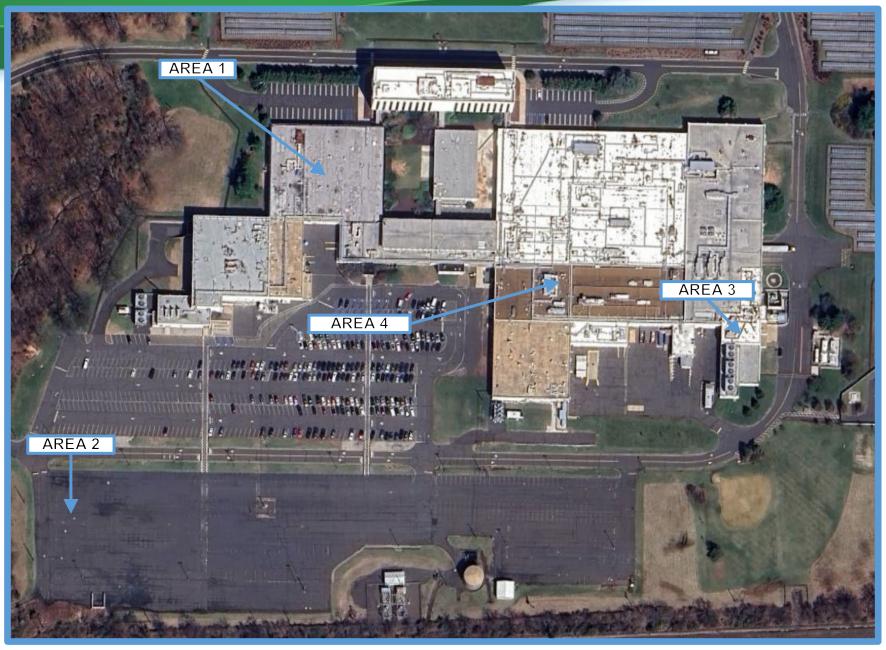
Additional cleanup activities for remaining four areas:

- Area 1: shallow soils in Building B Basement (AOC-16)
- Area 2: former septic field and underground storage tank (SWMU-8)
- Area 3: three former fuel oil underground storage tanks (SWMU-10)
- Area 4: Groundwater South of Building J (TCE Plume)

Remaining Areas Requiring

Cleanup Activities

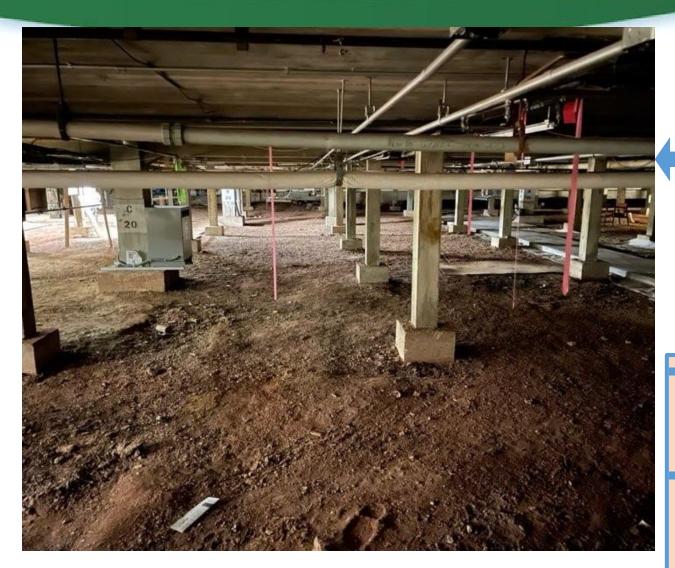
- Area 1: shallow soil in Building B Basement (AOC-16)
- Area 2: former septic field and underground storage tank (SWMU-8)
- Area 3: three former fuel oil underground storage tanks (SWMU-10)
- Area 4: Groundwater South of Building J (TCE Plume)



•AREA 1: Shallow Soil in B Basement (AOC-16)

Area 1: Shallow Soil in B Basement







- The "crawl space" within Building B basement and has low overhead clearance with an exposed dirt floor.
- Before 2006, the area was used to store utility supplies such as light bulbs, maintenance equipment, pipes, and fittings.
- This area in Building B basement is unoccupied, and access is restricted.

Area 1: Shallow Soil in B Basement



Investigation Activities

- Compounds with concentrations above cleanup levels in soil: metals, polycyclic aromatic hydrocarbons (PAHs), and poly-chlorinated biphenyls (PCBs)
 - Limited to top 18" of soil
 - Contained within the footprint of the B basement walls
 - No risk to groundwater, public, or individuals on site

Cleanup Plan

- Controls implemented to prevent exposure
 - Fencing and locked gates installed to restrict access
 - Place additional cover material over defined areas of shallow soil impacts
 - Deed Restriction for Building B Basement where soil is above cleanup levels

•AREA 2: Former Septic Field and Underground Storage Tank (UST) (SWMU-8)

Area 2: Former Septic Field and UST





LEGEND:

SHALLOW MONITORING WELL

INTERMEDIATE MONITORING WELL

DEEP MONITORING WELL

ENHANCED BIOREMEDIATION INJECTION WELL



- Former septic field (area approx. 30' x 30') located under paved asphalt parking lot; operated from 1966-71; abandoned in place
- UST and associated impacted soil removed in 1997
- Groundwater monitoring over 25+ years indicates contaminant concentrations have decreased by 80-100%
- Only PCE (tetrachloroethylene) remains above its cleanup level of 1 ppb at <u>one</u> shallow monitoring well (MW-32) at 1.8 ppb

Area 2: Former Septic Field UST



Investigation Activities

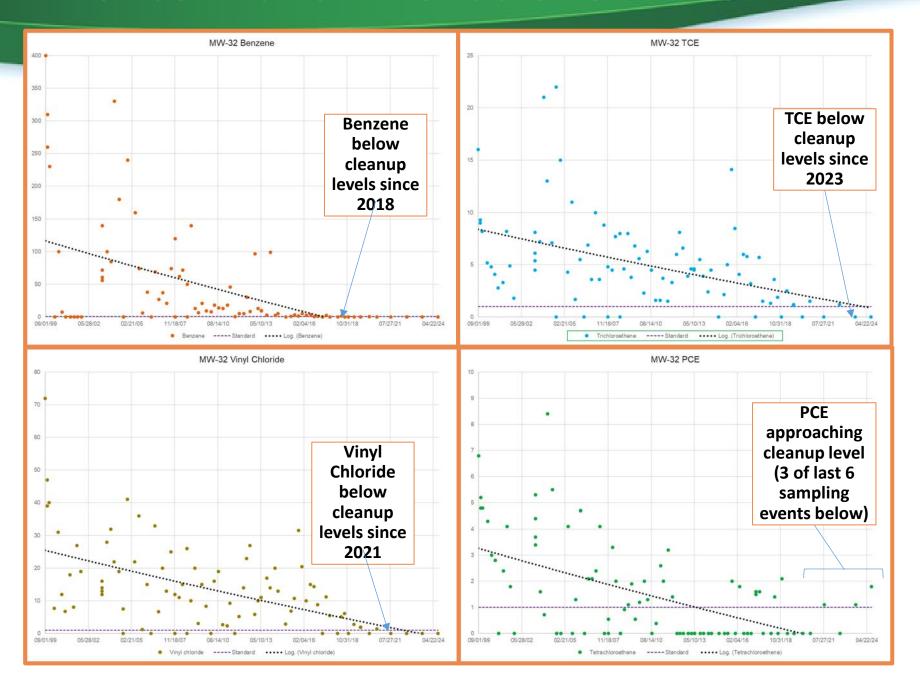
- Compounds with concentrations above cleanup levels:
 PCE, TCE (trichloroethylene), Vinyl Chloride, Benzene
- Extent of area with soil and groundwater impacts has been defined
 - All soil meets cleanup levels
 - Over the course of 25 years, the contaminants have broken down, and their presence has steadily declined to meet cleanup levels, except PCE.
 - Minimal PCE is still present; only in one monitoring well barely above the cleanup level.
- No off-site impacts or risk to public or individuals on site.

Cleanup Plan

- Continue annual groundwater monitoring to confirm levels continue to naturally decline
- Establish restrictions on groundwater use
- Submit annual report of groundwater monitoring results to the EPA

Area 2: Concentration Trends Over Time





•AREA 3: Three Former Fuel Oil Underground Storage Tanks (USTs) (SWMU-10)

Area 3: Three Former Fuel Oil USTs





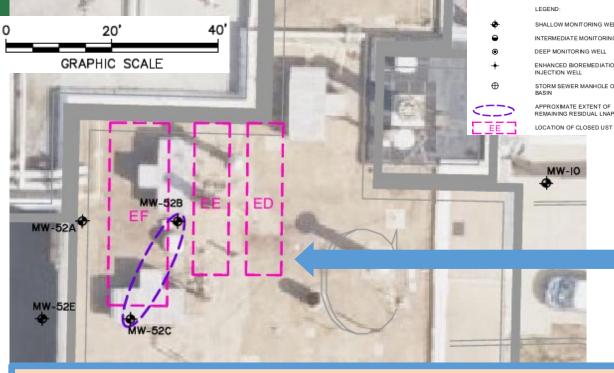


Three former fuel oil USTs under footprint of Bldg. C

- ➤ USTs formerly supplied fuel oil to the boilers and were taken out of service in 1986
- USTs closed (filled with cement) and received NJDEP approval in 1993

Area 3: Three Former Fuel Oil USTs





- Residual fuel oil confined within fill material surrounding former closed USTs; limited to two shallow groundwater monitoring wells within the former UST area
- Migration has been eliminated no risk to public or individuals on site.
- Routine fuel oil vacuum/removal events since 2018 have reduced the volume of fuel oil by 95%



Cleanup Plan:

- Deed Notice for soil to be filed due to access limitations
- Continued routine gauging and recovery of residual fuel oil, as needed
- Groundwater restrictions to be established where residual fuel oil is present
- Annual reporting of groundwater monitoring results to the EPA

•AREA 4: Groundwater South of Building J (TCE Plume)

Area 4: Groundwater South of Building J





Former Lyophilizer Unit



- TCE discovered during routine GW sampling of MWs in the early to mid-1990s
- 1998 GW investigation delineated TCE in shallow bedrock zone and identified likely source from a lyophilizer unit formerly housed in basement of Bldg. G
- Remedial program (addition of dilute food-grade molasses to groundwater) initiated in early 2000s to enhance the natural environment in breaking down the compounds

) Ai

Area 4: Groundwater South of Building J



Investigation Activities

- Compounds with concentrations above cleanup levels: PCE, TCE, cis-1,2-dichloroethylene (cis-DCE), 1,1-DCE, and Vinyl Chloride
- Extent of area with groundwater impacts has been defined
- Cleanup plan has been successful at reducing and controlling the contamination with the enhancement of molasses
 - Off-site concentrations are stable and continue to naturally decline
 - In the 20 yrs of groundwater monitoring, no products from the site have ever been found in groundwater samples at the farthest monitoring wells from the site boundary (~600 feet)

Cleanup Plan

- Continue remedial program with dilute food-grade molasses to enhance natural breakdown of compounds.
- Establish restrictions on groundwater use.
- Submit annual report of groundwater monitoring results to US EPA and NJDEP.

Area 4: TCE Trends 45,000 40,000 35,000 30,000 25,000 20,000 15,000 MW-39 SHALLOW MONITORING WELL INTERMEDIATE MONITORING WELL DEEP MONITORING WELL GRAPHIC SCALE INJECTION WELL



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Summary of Investigations & Actions



- Investigation Completed
 - 13 Solid Waste Management Units (SWMUs)
 - 20 Areas of Concern (AOCs)
 - 5 Industrial Site Recovery Act (ISRA) AOCs

Interim Corrective Measures (ICMs) Implemented

Presentation of Proposed HSWA Permit Mod

Proposed Cleanup (Corrective) Measures

- No Further Action (NFA)
 - SWMUs 1-7, 9, 11-13
 - AOCs 1-15, 17-19
 - ISRA AOCs 1-5
- Proposed Cleanup (Corrective) Measures
 - TCE Plume
 - SWMUs 8 (Southwest Leach Field) & 10 (3 No 6 Fuel Oil USTs)
 - AOC 16 (Soil in the Building Basement)



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The Value of Public Comments

The community stakeholders and the EPA benefit from:

- a better understanding of the RCRA implementation process.
- opportunities to influence the decision-making process.
- involvement in a process that builds cohesion and promotes community inclusiveness; and
- a corrective action approach that considers a community's needs and concerns and minimizes risks and negative impacts.



The Value of Public Comments (cont)

The EPA and the regulated facility also benefit from:

- improved access to local, anecdotal, and historical information about exposure pathways, unique ways in which the community uses local resources, and insight into community stakeholder interests and land use plans; and
- better understanding of community needs and concerns, values, cultures, habits and demographic characteristics.



Tips for Effective Public Comments

- Read the document and supporting resources that describe proposed EPA actions for which public comments are requested.
- Submit written comments that are clear, concise, relevant, and well documented.
- Identify the following: 1. the facility ID (from the EPA documents); 2. the specific document you are responding to; and 3. the date of the subject document.
- When referring to information from another report or document, cite the document name and date



Tips for Effective Public Comments (cont)

- When referring to a location onsite or off-site, try to describe it as precisely as you can
- There's no minimum or maximum length for an effective comment.
- As clearly as possible, explain why you agree or disagree with the proposals or plans, and provide an alternative or constructive modification to the EPA's proposed actions.
- Be concise but support your claims and use plain language.
- If you have questions or do not understand a part of the regulatory document, you may ask for help from the listed agency contact(s)

Next Steps



Written comments can be submitted through October 20 to:

Email Address

Park.Andy@epa.gov

OR

Physical Mailing Address

Andy Park
Land and Redevelopment Programs Branch
U.S. EPA Region 2
290 Broadway, 25th Floor
New York, NY 10007



Next Steps:

Written public comments accepted on the Proposed Permit Modification through October 20, 2025

The EPA will provide written responses to all relevant comments in a Responsiveness Summary that will accompany the issuance of a final permit modification.

Resources



QR Code to EPA's Website EPA Site Team Contacts



Andy Park

EPA Corrective Action Supervisor (212) 637-4184

Email: Park.Andy@epa.gov

Steven Petrucelli

Community Involvement Coordinator

Phone: (212) 637-4084

Email: Petrucelli.Steven@epa.gov

EPA's Website

www.epa.gov/hwcorrectiveactioncleanups/documents-ortho-clinical-diagnostics-raritan-new-jersey



Documents Available on EPA's Website Documents of Ortho-Clinical Diagnostics in Raritan, New Jersey

Some of Ortho-Clinical Diagnostics' key documents are accessible online:

- Environmental Indicator Human Exposures Ortho-Clinical Diagnostics, Raritan NJ (pdf) (193.33 KB)

 RCRA Environmental Indicator Human Exposures Under Control
- Environmental Indicator Groundwater Contamination Ortho-Clinical Diagnostics, Raritan NJ (pdf) (137.87 KB)

 RCRA Environmental Indicator Groundwater Contamination Under Control

Proposed Corrective Action Permit Modification - September 2025

- DCD Permit Modification-Public Notice-September 2025 (pdf) (184.28 KB)
- <u>CCD-Permit-Modification-Fact-Sheet-September 2025 (pdf)</u> (329.64 KB)
- CCD Permit Modification Proposed September 2025 (pdf) (2.02 MB)



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Questions?









- Place written questions in the Q&A box or click on Raise Hand to ask a question verbally
- Please state your name and affiliation before asking your question or making a comment.
- One question/comment at a time.



Closing

QR Code to EPA's Website

